Town of Arlington
Department of Health and Human Services
Office of the Board of Health
27 Maple Street
Arlington, MA 02476

Tel: (781) 316-3170
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Board of Health Meeting Agenda
Wednesday, April 11, 2018
Ground Floor Conference Room
Arlington Senior Center
5:30pm

I. Accept January 31, 2018 Meeting Minutes

II. Hearing: Tetragentics- 91 Mystic Street (Request to operate at BSL 2)

III. Hearing: Ink Jam- Park Ave (Variance Request for Apprenticeship)

IV. Hearing: Regulations Restricting the Sale of Tobacco and Nicotine Delivery Products

V. Discussion: Rock Removal Regulations

VI. Discussion: Draft Dumpster Regulations

VII. Discussion: Draft Regulation to Ensure the Sanitary and Safe Operation of Marijuana Establishments and the Sale of Marijuana

VIII. Discussion: Town Meeting Warrant Articles

IX. Arlington Youth Health and Safety Coaltion Updates

X. Environmental Updates
- Plastic Bag Ban
- Housing
- Nuisance

XI. Restaurant Updates
- Retail Food Standards

XII. Public Health Nurse Updates

XIII. Public Comment

Adjourn

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D R A F T
Board of Health Meeting Minutes
Wednesday, January 31, 2018
BOH Conference Room – Mural Room
Arlington Senior Center
5:30pm

Board Members in Attendance: Dr. Marie Walsh Condon, Mr. Kenneth Kohlberg, Dr. Kevin Fallon

Staff in Attendance: Natasha Waden, Director of Public Health; Kylee Sullivan, Health Compliance Officer; Padraid Martin, Lead Health Compliance Officer; Jessica Kerr, Public Health Nurse

Others in Attendance: James Quinn, Ink Jam Tattoo

Recording Secretary: Laura Munsey, Health & Human Services Administrative Assistant

Meeting called to order by Dr. Marie Walsh Condon at 5:35 pm.

Upon review of the December 6, 2017 meeting minutes, Mr. Kenneth Kohlberg requested minor editorial changes, (not affecting content) to the Draft Regulations Restricting the Sale of Tobacco and Nicotine Delivery Products – Section (E)13 and 14. This item will be tabled until the April 11, 2018 meeting for review as an agenda item.

A motion was made by Dr. Kevin Fallon, which was seconded by Mr. Kenneth Kohlberg to accept the December 6, 2017 meeting minutes as amended.

Vote: 3-0 in favor of the motion (Unanimous)

Update: Plastic Bag Ban

Inspector Martin informed the Board that the Plastic Bag Ban in Arlington will begin on March 1, 2018 for 10,000 Square Foot retailers and on July 1, 2018, for all other retailers. He stated notices have gone out, and the Health Department has met with each of the 10,000 square foot retailers regarding this implementation. The first week in February flyers will go out to retailers, and social media posts, and other methods of notification will go out to the public. Inspector Martin informed the Board that inspections will begin on March 1st, and reinspections will follow in April. A similar schedule will be implemented for the retailers with the July 1st start date.

Correspondence Received: Tattoo Apprentice

Mr. James Quinn, Owner of Ink Jam Tattoo Studio was invited to address the Board regarding his request that the Board of Health offer a Body Art Apprentice permit within the regulations. Inspector Sullivan informed the Board that the under the Town's current regulations, permits are issued to establishments and practitioners only. Practitioners require 2 years experience before being granted a permit. She further stated that the Massachusetts Department of Public Health has model regulations for establishments and practitioners, however not for apprentices. Mr. Quinn provided copies of three (3) communities that do offer Apprentice permits, including Cambridge, Medford, and Lowell. Inspector Sullivan also stated that she has had an opportunity to review those regulations, and feels confident that Arlington could incorporate language within the Regulations if the Board so requested.

Director Waden informed the Board that Mr. Quinn manages an extremely well run business that has been in town for 12 years and it is apparent that cleanliness and safety are top priorities. She further stated Mr. Quinn meets and exceeds the procedures and guidelines referenced in the current regulations. Director Waden informed the Board that Mr. Quinn approached the Board and made a similar request for a Body Art Apprentice Permit in 2006, at which time the Board agreed to take the matter under consideration for future action.

Mr. Quinn stated that Arlington sets high standards, and he is proud of that. He stated he is addressing the Board, because he would like to hire an apprentice, Ms. Ismini Vocas, at his establishment. He stated body art is a practice taught through mentors, and he learned his craft from many wonderful individuals in the field.

The Board informed Mr. Quinn of options available including requesting a possible variance for his establishment, and/or request a revision to the existing regulations to include an apprentice permit license. It was agreed that Mr. Quinn will work with the staff at the Health Department, and present a formal request at the April 11, 2018 Board of Health Meeting.

Annual Report

Inspector Martin shared the following highlights of the 2017 Annual Report including:

- The Health Department cosponsored two (2) animal rabies vaccination clinics with Animal Control
- Staff investigated fourteen (14) food complaints and held five (5) administrative meetings to discuss food safety issues
- Twenty (20) new food establishments opened or changed owndership, including four (4) residential kitchens, and thirteen (13) establishments closed.
- Staff conducted 160 housing inspections, condemned two (2) properties and referred five (5) cases to the Attorney General's Abandoned Housing Initiative Program.
- The Hoarding Response Team received eighteen (18) referrals and identified five (5) new hoarding cases, while conducting follow-up on eight (8) ongoing cases.
- The Health Department issued 428 Permits
- The Health Department conducted 1,105 Inspections

Public Health Nurse, Jessica Kerr, reported 269 Communicable Diseases have been investigated and monitored.

Environmental Updates

Inspector Martin informed the Board that members of the Health Department have met with Charlotte Milan, and will provide a copy of the Draft Dumpster Regulations to the Board for review and discussion at the April 11, 2018 Meeting.

Retail Food Standards

Director Waden updated the Board on the progress made regarding the AFTO Grant Retail Food Standards 1, 3, and 4. She stated the Department will be in compliance with standards 1 and 3 by the end of April, and are well on the way to full compliance with Standard 4. Because the Board has agreed to adopt the 2013 Food Code, the Department filed for an extension for Standard 4.

Housing

The Health Department filed a criminal complaint regarding 1530 Massachusetts Avenue, which has been Condemned by the Board of Health. Since that filing, much progress has been made on the exterior of the property and the owner is moving forward towards compliance in the interior.

Additional abandoned properties have been forwarded to the Attorney General's Abandoned Housing Initiative Program.

Director Waden informed the Board that the resources made possible through the Attorney General's Abandoned Housing Initiative have been extremely beneficial to the Town, and it has proven to be a great and valuable partnership.

Restaurant Updates

Inspector Martin informed the Board of nine (9) permited food establishment closures including:

- Arlington Food Pantry (closed the Marathon Street location)
- 2 Establishments at the Local Fare closed: Boston Bonbon and Awake Nitro Brewing
- 2 Residential Kitchens closed: Bobbies Additions, Pingping, and Poppy & Ma's
- Dearborn Academy (moved to Newton)
- La Posada (Closed)
- Bistro Duet (Closed)

New additions at the Local Fare include:

- Mass Hole Donuts
- Beacon Blend

Plan reviews received for:

- Little Joes (Change of Ownership)
- Arlington Liquors (Change of Ownership)
- 478 Mass Ave
- Brit Bakery (at the Local Fare)

Public Health Nurse Updates

Nurse Kerr informed the Board that it has been an extremely active flu season, and Arlington has 38 "Confirmed" cases of the flu including 2 children. She reported the Health Department has vaccinated over 1,250 residents, and has been offering flu vaccination appointments to residents at the Health Office, which has generated an additional 60 vaccinations administered in the past 2 weeks.

Nurse Kerr updated the Board on 1 isolated case of MRSA at Arlington High School, and stated best practices were followed, and this matter was handled well.

Public Comment

None

Meeting was adjourned at 6:55 pm

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MEMO

To: Board of Health Members
From: Padraig Martin, Health Compliance Officer
Date: April 5, 2018
RE: TetraGenetics

TetraGenetics is a permitted biotechnology company operating in Arlington, MA since 2015. There have been no known incidents during their time operating in Arlington. They currently operate as a Biosafety Level 1 (BSL-1) laboratory, which is defined in part by the U.S. Department of Health and Human Services, Biosafety in Microbiological and Biomedical Laboratories (BMBL) as "suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment."

On Tuesday, February 20, 2018, the Health Department received correspondence from TetraGenetics requesting to add a Biosafety Level 2 (BSL-2) room to their existing laboratory located at 91 Mystic Street, Arlington, MA. The BMBL states in part that "BSL-2 is suitable for work involving agents that pose moderate hazards to personnel and the environment." This change would allow TetraGenetics to culture transfected mammalian cells such as HEK293 and Jurkat.

On Tuesday, March 19, 2018, Natasha Waden, Director of Public Health, and Padraig Martin, Lead Health Compliance Officer, met with Elizabeth Graham, Consulting Safety Officer with Safety Partners Inc., as well as Paul Colussi, Vice President of Research, and Joanna Cardarelli, Research Associate, from TetraGenetics, to discuss the proposed changes. It was agreed that an updated safety manual and employee training information be submitted to the Health Department, and that representatives from TetraGenetics appear before the Board of Health at the April 11th meeting to present the proposed changes and answer any questions.

Upon review of the information submitted by TetraGenetics we found the laboratory design, space, security, safety manual and employee training to be adequate, with one exception. The proposed design uses a hand-sanitizer dispenser in lieu of a handwashing sink. According to the guidelines spelled out in the BMBL "Secondary barriers, such as hand washing sinks and waste decontamination facilities, must be available to reduce potential environmental contamination." However, representatives from Tetragentics reported that some communities have found hand-sanitizer to be an acceptable alternative. We hope to provide more clarification on this matter at the next Board meeting.

Biological Safety Manual & Exposure Control Plan

TetraGenetics

TetraGenetics Inc.

91 Mystic Street
Arlington, MA 02474

April, 2018

Biological Safety Manual & Exposure Control Plan

The following Biological Safety Manual & Exposure Control Plan dated April, 2018, as written, has been approved by:

Signature: _____

Date: _____

Title: _____

Print Name: _____

1. PURPOSE

TetraGenetics Inc. is committed to the prevention of employee exposures to biohazardous materials, including human source material such as blood, serum, tissue, human cell lines and any other potentially infectious material to which an employee may be exposed as a result of his or her job requirements. In order to reduce or eliminate the hazards of occupational exposure, TetraGenetics has implemented this Biological Safety Manual & Exposure Control Plan (ECP) to provide details on safety guidelines and employee protection measures. This manual explains the use of various engineering and work practice controls, including the use of personal protective equipment, housekeeping requirements, medical surveillance, and Hepatitis B vaccination programs as they apply to the work done on-site. Also addressed, are the means by which the existence of hazards to employees is communicated, including labels and signs, recordkeeping and training.

This plan was developed in accordance with the OSHA "Occupational Exposure to Bloodborne Pathogens: Final Rule" in 29 CFR 1910.1030, to minimize or eliminate employee exposure to bloodborne pathogens and other biological hazards. A copy of this OSHA Standard is located next to the printers in the back lab office and online at www.osha.gov.

This manual applies to laboratory research, service and support activities that may involve exposure to biohazardous agents or materials and that come under the purview of the Biological Safety Officer. The manual is intended to give an overview of biological safety and to provide compliance with the OSHA Bloodborne Pathogens Standard. It is not meant to be an extensive guide for experiment-specific processes or provide specific safety protocols for all biological materials. In these cases, the Biological Safety Officer must perform a specific Job Safety Analysis that results in written procedures and training. This information can then be added to this manual as appendices, or kept separately in the safety files.

2. RESPONSIBILITIES

Biological Safety Officer (BSO)

As the official representative of the company, the Biological Safety Officer has biological safety overview of all ongoing scientific projects in the company. The BSO will provide guidance to all Principal Investigators, Supervisors and Employees of laboratories performing biological work.

The BSO will ensure compliance with the Centers for Disease Control (CDC) and National Institutes of Health (NIH) publications, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL) and the *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, as appropriate. The BSO will ensure adherence and compliance with any local regulations regarding biological safety.

The BSO will be an active participant on the Institutional Biosafety Committee (IBC).

The BSO will conduct an annual review and update of this manual. This will include information that reflects any changes in technology that eliminates or reduces occupational exposure by:

1. Implementing a safer sharps program that evaluates lab innovations and technological developments that reduce the risk of exposure, particularly medical devices designed to reduce needlesticks
2. Documenting the consideration and use of appropriate, commercially-available, and effective safer devices by describing the devices identified as candidates for use, the method used to evaluate those devices, and the justification for the eventual selection. The documentation can be done by listing the employees involved and describing the process by which input was requested; or through other documentation, including references to the minutes of meetings, copies of documents used to request employee participation, or records of responses received from employees.

Principal Investigator (PI)

A PI will ensure compliance with the Arlington Board of Health, NIH guidelines and OSHA regulations, when work with regulated biological agents such as recombinant DNA, human source materials, or other potentially infectious material (OPIM) is conducted. The PI will register all work involving recombinant DNA with the Institutional Biosafety Committee (IBC) Chairperson.

The PI that oversees a project will ensure that all employees have project specific training for each particular experiment. The PI must ensure biological and physical containment conditions are maintained, such as strain or phenotype purity, proper practices, techniques and equipment.

Supervisors

Supervisors will assess all potentially hazardous agents involved in work activities within their laboratories and institute appropriate safeguards. Supervisors will have experiment specific protocols for biohazardous work which include measures for minimizing exposure incidents, informing personnel of potential hazards and the basis for assessing hazards, assuring proficiency of staff and maintaining and updating these protocols on a continuing basis.

Supervisors will ensure that their employees receive the proper training, follow all safety policies, report incidents and correct non-compliance issues as indicated by the BSO or Safety Committee. Supervisors must also ensure that all employees with the potential for occupational exposure to bloodborne pathogens follow the provisions of this plan and manual. This includes providing a copy of this Biological Safety Manual & Exposure Control Plan to those employees, requiring that they attend an annual training session, enforcing compliance with this plan, ensuring that new employees who will have occupational exposure are properly trained, and performing follow-up procedures for all exposure incidents.

Employees

Employees are to perform tasks and procedures in a manner that minimizes or eliminates their own and others' exposure and to perform duties as established in this Biological Safety Manual & Exposure Control Plan and as trained. It is the employee's responsibility to report any incidents, accidents, exposure or needlesticks to their supervisor and the BSO immediately. All incidents must be documented by the employee on an incident report within 24 hours.

3. RISK AND CONTAINMENT LEVELS

Risk Groups

The American Biological Safety Association (ABSA, https://www.absa.org/), NIH and the Canadian Laboratory Biosafety Guidelines have categorized risk group for biological organisms.

Risk Group 1- low individual and community risk
A biological agent:

1. That is well-characterized and not known to consistently cause disease in healthy adult humans
2. That poses little risk to the environment

Risk Group 2 - moderate individual risk, limited community risk
A biological agent:

1. That can cause human disease and might be a hazard to workers
2. That is unlikely to spread to the community
3. For which there is usually effective prophylaxis or treatment available

Risk Group 3 - high individual risk, low community risk
A biological agent:

1. That can cause severe or lethal human disease and present a serious hazard to workers
2. That may present a risk of spreading to the community
3. For which there may be effective prophylaxis or treatment available

Risk Group 4 - high individual risk, high community risk
A biological agent:

1. That causes severe or lethal human disease and is a serious hazard to workers
2. That may present a high risk of spreading to the community
3. For which there is usually no effective prophylaxis or treatment available

Risk Assessment

In order to assess a biohazard and provide adequate containment, it is necessary to identify the risk group of an organism and then perform a risk assessment of the experimental situation. To assess occupational risk while working with biohazardous materials and to understand what types of containment are necessary, five factors must be considered before a decision is made:

1. What is the infectious dose of the organism?
2. What are the likely routes of entry?
3. What is the viability of the organism in specific environments?
4. Are suitable disinfectants available for the organism?
5. Is effective prophylaxis available?

After a risk assessment is performed, a physical containment level is assigned to the work being performed with that organism. It is important to note that although, risk group and biosafety level often coincide (i.e. risk group 1 organisms are handled at biosafety level 1) this is not always the case. Only a full risk assessment can determine the containment level for each biological agent in use in the laboratory.

When cell cultures are known to contain an etiologic agent, an oncogenic virus or amphotropic packaging system, the cell line must be classified at the same level as that recommended for the agent. This is the same for all cell cultures purposely inoculated with an infectious agent. An example is immortalized cells (also known as continuous or permanent cell lines). These are obtained by isolating cells from tumors, by mutating primary cells with mutagens, or using viruses or rDNA to generate indefinitely growing cells. Hybridoma cell lines are immortalized cell lines created by fusion of primary cells with a continuous cell line. In general, primary cell cultures are less characterized than permanent cell lines and are not typically tested for contaminating pathogens. Tumorigenic potential is a risk to consider with permanent cell lines.

Containment

Four levels of biosafety controls have been defined by the Centers for Disease Control (CDC) and the National Institutes of Health (NIH). They are combinations of lab practices, techniques, safety equipment and the physical design of the lab facility. Experience has shown that strict adherence to these guidelines contributes to a healthier and safer environment, both in the work place and in the surrounding community.

Biosafety physical containment levels and related safety practices may be applied to work with all types of biohazardous materials, such as genetically manipulated cell lines, potentially infectious human or animal body fluids and tissues, bacterial or viral cultures and live animals.

An in-depth description of biosafety containment levels 1 and 2 is given below because these are the two levels most commonly used. A table which summarizes the basics of all four biosafety levels is provided in Appendix 1. These descriptions are taken directly from the CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf. Additional information on BL3 and BL4 can be found in the BMBL as well.

Biosafety Level One (BL1)

Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment. BL1 laboratories are not necessarily separated from the general traffic patterns in the building. Work is typically conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required, but may be used as determined by appropriate risk assessment. Laboratory personnel must have specific training in the procedures conducted in the laboratory and must be supervised by a scientist with training in microbiology or a related science.

The following standard practices, safety equipment, and facility requirements apply to BL1:

A. Standard Microbiological Practices

1. The laboratory supervisor must enforce the institutional policies that control access to the laboratory.
2. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:
    a. Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
    b. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
    c. Non disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
    d. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plasticware should be substituted for glassware whenever possible.
6. Perform all procedures to minimize the creation of splashes and/or aerosols.
7. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
8. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport:
    a. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
    b. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
9. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. The sign may include the name of the agent(s) in use, and the name and phone number of the laboratory supervisor or other responsible personnel. Agent information should be posted in accordance with the institutional policy.
10. An effective integrated pest management program is required.

11. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of child-bearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

B. Special Practices

None required.

C. Safety Equipment (Primary Barriers and Personal Protective Equipment)

1. Special containment devices or equipment, such as BSCs, are not generally required.
2. Protective laboratory coats, gowns, or uniforms are recommended to prevent contamination of personal clothing.
3. Wear protective eyewear when conducting procedures that have the potential to create splashes of microorganisms or other hazardous materials. Persons who wear contact lenses in laboratories should also wear eye protection.
4. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Wash hands prior to leaving the laboratory. In addition, BL1 workers should:
    a. Change gloves when contaminated, integrity has been compromised, or when otherwise necessary.
    b. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
    c. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.

D. Laboratory Facilities (Secondary Barriers)

1. Laboratories should have doors for access control.
2. Laboratories must have a sink for hand washing.
3. The laboratory should be designed so that it can be easily cleaned. Carpets and rugs in laboratories are not appropriate.
4. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
    a. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
    b. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.

5. Laboratories windows that open to the exterior should be fitted with screens.

Biosafety Level 2 (BL2)

Biosafety Level 2 builds upon BL1. BL2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BL1 in that 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in BSCs or other physical containment equipment.

The following standard and special practices, safety equipment, and facility requirements apply to BL2:

A. Standard Microbiological Practices

1. The laboratory supervisor must enforce the institutional policies that control access to the laboratory.
2. Persons must wash their hands after working with potentially hazardous materials and before leaving the laboratory.
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption must not be permitted in laboratory areas. Food must be stored outside the laboratory area in cabinets or refrigerators designated and used for this purpose.
4. Mouth pipetting is prohibited; mechanical pipetting devices must be used.
5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware must be developed and implemented. Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries. Precautions, including those listed below, must always be taken with sharp items. These include:
    a. Careful management of needles and other sharps are of primary importance. Needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal.
    b. Used disposable needles and syringes must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal.
    c. Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.
    d. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plasticware should be substituted for glassware whenever possible.
6. Perform all procedures to minimize the creation of splashes and/or aerosols.
7. Decontaminate work surfaces after completion of work and after any spill or splash of potentially infectious material with appropriate disinfectant.
8. Decontaminate all cultures, stocks, and other potentially infectious materials before disposal using an effective method. Depending on where the decontamination will be performed, the following methods should be used prior to transport:

   a. Materials to be decontaminated outside of the immediate laboratory must be placed in a durable, leak proof container and secured for transport.
   b. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
9. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. Posted information must include: the laboratory's biosafety level, the supervisor's name (or other responsible personnel), telephone number, and required procedures for entering and exiting the laboratory. Agent information should be posted in accordance with the institutional policy.
10. An effective integrated pest management program is required.
11. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of child-bearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

B. Special Practices

1. All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements.
2. Laboratory personnel must be provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the laboratory.
3. Each institution must establish policies and procedures describing the collection and storage of serum samples from at-risk personnel.
4. A laboratory-specific biosafety manual must be prepared and adopted as policy. The biosafety manual must be available and accessible.
5. The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BL-2 agents.
6. Potentially infectious materials must be placed in a durable, leak proof container during collection, handling, processing, storage, or transport within a facility.
7. Laboratory equipment should be routinely decontaminated, as well as, after spills, splashes, or other potential contamination.
   a. Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious material.
   b. Equipment must be decontaminated before repair, maintenance, or removal from the laboratory.
8. Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the laboratory biosafety safety manual. All such incidents must be reported to the laboratory supervisor. Medical

evaluation, surveillance, and treatment should be provided and appropriate records maintained.

9. Animals and plants not associated with the work being performed must not be permitted in the laboratory.
10. All procedures involving the manipulation of infectious materials that may generate an aerosol should be conducted within a BSC or other physical containment devices.

C. Safety Equipment (Primary Barriers and Personal Protective Equipment)

1. Properly maintained BSCs (preferably Class II), other appropriate personal protective equipment, or other physical containment devices must be used whenever:
    a. Procedures with a potential for creating infectious aerosols or splashes are conducted. These may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonicating, opening containers of infectious materials, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.
    b. High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups.
2. Protective laboratory coats, gowns, smocks, or uniforms designated for laboratory use must be worn while working with hazardous materials. Remove protective clothing before leaving for non-laboratory areas (e.g., cafeteria, library, administrative offices). Dispose of protective clothing appropriately, or deposit it for laundering by the institution. It is recommended that laboratory clothing not be taken home.
3. Eye and face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms must be handled outside the BSC or containment device. Eye and face protection must be disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses in laboratories should also wear eye protection.
4. Gloves must be worn to protect hands from exposure to hazardous materials. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Gloves must not be worn outside the laboratory. In addition, BSL-2 laboratory workers should:
    a. Change gloves when contaminated, integrity has been compromised, or when otherwise necessary. Wear two pairs of gloves when appropriate.
    b. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
    c. Do not wash or reuse disposable gloves. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.
5. Eye, face and respiratory protection should be used in rooms containing infected animals as determined by the risk assessment.

D. Laboratory Facilities (Secondary Barriers)

1. Laboratory doors should be self-closing and have locks in accordance with the institutional policies.
2. Laboratories must have a sink for hand washing. The sink may be manually, hands-free, or automatically operated. It should be located near the exit door.
3. The laboratory should be designed so that it can be easily cleaned and decontaminated. Carpets and rugs in laboratories are not permitted.
4. Laboratory furniture must be capable of supporting anticipated loads and uses. Spaces between benches, cabinets, and equipment should be accessible for cleaning.
    a. Bench tops must be impervious to water and resistant to heat, organic solvents, acids, alkalis, and other chemicals.
    b. Chairs used in laboratory work must be covered with a non-porous material that can be easily cleaned and decontaminated with appropriate disinfectant.
5. Laboratory windows that open to the exterior are not recommended. However, if a laboratory does have windows that open to the exterior, they must be fitted with screens.
6. BSCs must be installed so that fluctuations of the room air supply and exhaust do not interfere with proper operations. BSCs should be located away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions.
7. Vacuum lines should be protected with High Efficiency Particulate Air (HEPA) filters, or their equivalent. Filters must be replaced as needed. Liquid disinfectant traps may be required.
8. An eyewash station must be readily available.
9. There are no specific requirements on ventilation systems. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory.
10. HEPA filtered exhaust air from a Class II BSC can be safely re-circulated back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer's recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or a direct (hard) connection. Provisions to assure proper safety cabinet performance and air system operation must be verified.
11. A method for decontaminating all laboratory wastes should be available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).

There are no specific ventilation requirements. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory. If the laboratory has windows that open to the exterior, they are fitted with fly screens.

A brief explanation of the remaining biosafety levels is given below. Appendix 1 gives a summary overview of all 4 levels.

BL2 Enhanced (BL2+)

This level is not described in the BMBL, but is often used as a hybrid safety level between BL2 and BL3. With this level, there is work done with materials that may be infectious primarily via an aerosol and introduction through the skin or mucous membranes. Biological agents handled at BL2 enhanced generally pose a non-serious, non-fatal disease risk. Risk is elevated above basic BL2 due to the insert location, vector or cell line. At this level, risk can be controlled by strict adherence to Enhanced BL2 practices within a physical BL2 laboratory. Specific lab practices and experimental procedures must be outlined in a working protocol for the laboratory as the result of a specific Risk Analysis. General BL2 Enhanced working procedures are given in Appendix 2.

Biosafety Level Three (BL3)

This level identifies an inhalation exposure risk. Risk group 3 agents which are highly infectious and for which treatment may not be available are used. As examples, tuberculosis and anthrax are used in BL3 containment. Work at BL3 is allowed in some cities under separate permit from the municipal regulatory bodies. A secure and controlled laboratory environment is required. See the BMBL for specific physical laboratory requirements and practices.

Biosafety Level 4 (BL4)

This is the highest containment level as described by the CDC/NIH. Risk Group 4 agents which are extremely infectious are used at BL4 containment; examples are Ebola and Variola virus. BL4 work is prohibited in most cities. See the BMBL for specific physical laboratory requirements and practices. Work at BL4 is prohibited in the town of Arlington.

4. HUMAN MATERIALS AND OPIM

The OSHA Bloodborne Pathogen Standard defines safety requirements for working with human blood and other clinical materials, human immunodeficiency virus, and the bloodborne hepatitis viruses. Those safety requirements are described in this Biosafety Manual and Exposure Control Plan. Before working with any human materials, contact the Biosafety Officer for guidance and to schedule Bloodborne Pathogens training.

The Standard establishes the principle that blood and certain body fluids of all human beings are considered potentially infectious for bloodborne pathogens such as hepatitis B or C virus (HBV, HCV) and human immunodeficiency virus (HIV).

It further establishes that universal precautions are to be used to prevent parenteral, mucous membrane, and non-intact skin exposure to bloodborne pathogens when handling the following human materials: blood; tissues; body fluids containing visible blood; semen; vaginal secretions; cerebrospinal, synovial, pleural, peritoneal, pericardial, and amniotic fluids; HIV, HBV and HCV infected cells and animals; and saliva in dental procedures.

Universal precautions do not apply to the following human materials: urine, feces, sputum, saliva, tears, sweat, nasal secretions, and vomitus. While these materials are not covered by the bloodborne pathogens standard, they may be contaminated with infectious microorganisms and can present a potential hazard to persons working with them. Prudent handling practices are recommended for work with any human material.

Materials other than those mentioned above which should also be handled at BL2 containment using universal precautions are:

1. Human derived cell lines
2. Human cell strains
3. Human serum derived reagents

Human Cell Lines

Characterization of human cells, for inclusion or exclusion from compliance with the Bloodborne Pathogens Standard, would include screening of the cells lines for viruses characterized as bloodborne pathogens by the Standard, including human immunodeficiency viruses, hepatitis viruses and EBV, if the cells are capable of propagating such viruses. Testing may include antigenic screening for viral or agent markers, co-cultivation with various indicator cells that allow contaminants to grow, or using molecular technology such as polymerase chain reaction or nucleic acid hybridization, to identify latent viruses capable of infecting humans. These are viruses such as Herpesviruses like Epstein Barr Virus, or papilloma members of the Papovavirus group. Cell lines that are procured from commercial vendors or other sources with documented testing to be free of human bloodborne pathogens and which have been protected by the employer from environmental contamination may be excluded from the Bloodborne Pathogens Standard.

It should be noted that human cells or other transformed human cell lines are sometimes adulterated with laboratory pathogens accidentally introduced by cultivation with other cell cultures, or physically contaminated by other cell cultures handled in the same lab. In order to handle human cells, without having to comply with the requirements of the Bloodborne Pathogens Standard, human cells should be documented to be pure cells and shown to be free of Bloodborne Pathogens by testing as explained above. Even common cell lines, such as human cervical carcinoma cells, known as HeLa cells, would need documentation on purity prior to downgrading. Please note that if a cell line is proven to be BBP free, it may be removed from the requirements of the Bloodborne Pathogen Standard, but a full risk assessment would be required to also downgrade the material to BL1.

Human Cell Strains

All primary human cell **explants** from tissues and **subsequent in vitro** passages of human tissue explant cultures, also known as human cell strains, must be regarded as containing potential bloodborne pathogens and should be handled in accordance with the Bloodborne Pathogens Standard. Non-transformed, human cell strains, characterized by documented, reasonable laboratory testing as described for human cell lines, to be free of human immunodeficiency virus, hepatitis viruses, or other bloodborne pathogens may be exempted from the standard's requirements. However, if such tissue explants or subsequent cultures are derived from human subjects known to carry bloodborne pathogens, such as hepatitis viruses or human immunodeficiency viruses or are deliberately infected with bloodborne pathogens, they must be handled in accordance with the precautions noted in the Bloodborne Pathogens Standard. Likewise, animal tissues, explants or cell cultures known to be contaminated by deliberate infection with human immunodeficiency virus or Hepatitis B virus are also subject to the Standard.

Human Derived Reagents

The Centers for Disease Control cautions that all human-serum-derived reagents used in the lab, such as Human Serum Albumin (HSA), be handled at BL2 levels with universal precautions because no test method can offer complete assurance that laboratory specimens do not contain HIV, hepatitis B virus, or other infectious agents.

5. RECOMBINANT DNA (rDNA)

Research with recombinant DNA molecules is regulated typically by two organizations: the National Institutes of Health (NIH) and the local Board of Health. For facilities receiving federal funds for rDNA research, adherence to the NIH Guidelines are mandatory, even for projects at the same facility which are not funded by the NIH. For facilities that do not receive federal funding, the local Board of Health is the primary regulatory agency. Each Board of Health may have its own ordinance which requires a facility to abide by the NIH Guidelines in total, or in part. A copy of the NIH Guidelines can be found in TetraGenetics central Safety files which are located in the main lab, and online at http://osp.od.nih.gov/sites/default/files/NIH_Guidelines.html. The General Ordinance for the City of Arlington can be found in Appendix 3.

NIH Guideline Requirements

Establish an Institutional Biosafety Committee (IBC)

TetraGenetics shall establish an IBC and procedures that the IBC will follow in its review of project registration proposals and activities. Formal minutes of the IBC meetings will be written and kept on file at the institution. These minutes will not contain proprietary company information and therefore will be made available to the public as requested. The City of Arlington requires that IBC minutes be submitted to the Board of Health Director by April 30th of each year.

An IBC will be comprised of no fewer than five members with collective expertise and experience with rDNA technology, the ability to assess safety and identify potential risk to workers and the environment, and expertise in physical containment. At least one member of the committee must be from the laboratory technical staff. One member can be a consultant knowledgeable in institutional policies, applicable law, and the environment. Membership must also include:

1. At least two members not associated with the institution who will act as "Community Representatives"; at least one member will be an Arlington resident, approved by the Board of Health.
2. An expert in plants, plant pathogens and plant pest containment principles when plants are proposed for use in the registration;
3. An expert in animal containment principles when animals are proposed for use in the registration;
4. The Biological Safety Officer
5. Participants with adequate expertise and training if human subjects are involved.

The IBC will review and assess all registrations for safety and will ensure that all projects conform with the Guidelines. The initial and periodic review will include an assessment of the appropriate containment level required by the Guidelines for the proposed research and an

assessment of the facilities, procedures, practices, training and expertise of recombinant DNA personnel, and will recommend emergency plans and appropriate medical surveillance for the personnel.

Project Registrations

All Principal Investigators planning to work with rDNA must complete a Project Registration document prior to beginning work. This registration must be approved by the Institutional Biosafety Committee prior to initiation. The rDNA project registration form is given in Appendix 4.

Training for Employees

All employees involved in recombinant DNA research will be given biological safety training. In addition, project specific training will be provided by the Principal Investigator of the project before initiating work.

Medical Surveillance

Medical surveillance for each project will be decided upon by the IBC. Project specific medical surveillance programs will be included on the registration document.

Accident/Incident Reports

Any accidents, illnesses, releases, or significant problems that occur while working with recombinant DNA will be reported to the Office of Recombinant DNA Activities and the Arlington Board of Health.

Retroviruses

Retroviral vectors are a common tool used in cell biology. Retroviruses package RNA molecules into virus particles and express a messenger RNA of interest. The retroviral genome expressed in packaging cell lines is not intact, therefore no replication competent virus (RCV) is produced. Because of this, virus particles are "infectious" for only one replication cycle. However, the possibility exists for recombination with endogenous retroviral elements, or with an exogenous retroviral infection, such as HIV. This is the primary risk when using retroviral vectors.

Another risk involved with retroviral vectors is the target cell range of the vector. For example: if RNA is packaged in particles with the envelope protein of vesicular stomatitis virus (VSV-G protein) this provides a broad target cell range because most cell types express the phospholipids to which VSV-G protein binds. Appendix 5 describes a variety of common retroviral vectors.

Viral vectors are not currently used at TetraGenetics; and there are not plans for future use at this time.

6. SELECT AGENTS

The Centers for Disease Control (CDC) regulation: Requirements for Facilities Transferring or Receiving Select Agents (42 CFR 72.6), was developed in response to The United States Antiterrorism and Effective Death Penalty Act. The CDC regulation was implemented to reduce the risk that terrorists, or others with illicit intentions, would gain access to, and misuse, such materials. It addresses the domestic shipment and handling of certain infectious agents and toxins. The CDC list of select agents that cause substantial harm to human health can be found in Appendix 6 of this manual. A permit must be obtained from the CDC before these agents may be shipped or received. In order to obtain a permit for Select Agents, the facility must be registered and create a Select Agents program. This manual does not cover a Select Agents program; for more details go to http://www.selectagents.gov/.

7. EXPOSURE DETERMINATION

The OSHA Bloodborne Pathogens Standard requires that an exposure determination be performed in laboratories where human source materials are used. A list of departments, job classifications, tasks and responsibilities must be made to identify all employees that may have exposure to human materials.

Job Classifications

Employees of the following departments may have exposure to human source materials:
Genetics
Immunology
Molecular biology

The potential for occupational exposure to blood and other potentially infectious material may occur with these job classifications:
Research Associate
Research Scientist I
Research Scientist II
Head of Genetics
Associate Director
Vice President of Research

Tasks and Procedures

The following tasks or procedures may cause potential exposures to personnel listed in the above job classifications:
Work with human cell lines
Shipping or receiving human source materials
Closing up, boxing or moving biomedical waste containers

8. ENGINEERING CONTROLS

Engineering and work practice control measures are to be used to minimize, isolate, or eliminate employee exposure for each task within the work area. Such control measures are listed below. ***Engineering controls must be the primary means of eliminating or minimizing employee exposure and include the use of safer medical devices, such as needleless devices, shielded needle devices, plastic capillary tubes and retractable scalpel/knife blades.*** When occupational exposure remains after institution of these controls, personal protective equipment is used. Engineering controls are used when there is reasonable likelihood of occupational exposure. Engineering controls are examined, and maintained or replaced, on a regular schedule by the supervisor and employee to ensure their effectiveness. Current regulations state that "safer medical devices, such as sharps with engineered sharps injury protections and needleless systems" constitute engineering controls and thus must be used where feasible.

It is important to note that each lab employee is responsible for reviewing the effectiveness of the engineering controls before use. The Biosafety Officer is responsible for ensuring biosafety cabinets are certified on an annual basis.

The Biosafety Cabinet (BSC)

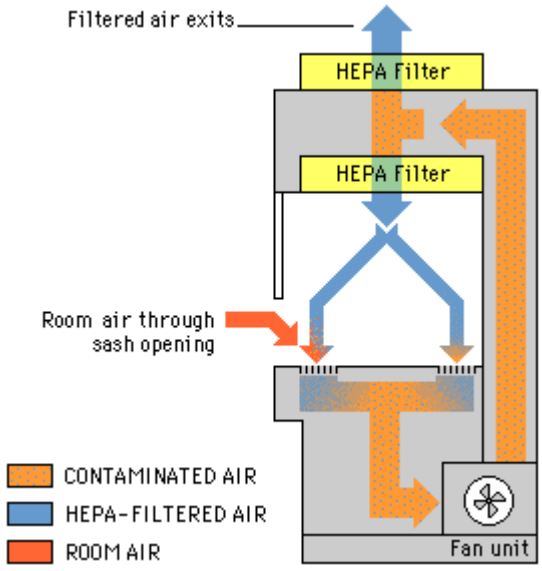
Biosafety cabinets are the primary control against potential aerosol exposure. They are primary containment devices designed to provide protection for both the worker and the environment, as well as provide a work environment free of contaminants. There are many types of BSCs available which offer various levels of protection. Information about the variety of types of biosafety cabinets can be found at http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_appendixA.pdf.

Biosafety cabinets are certified once per year at a minimum, or after a cabinet has been moved within the facility or decontaminated.

Each BSC is examined and disinfected after each scientific procedure. The functionality of the HEPA filter is checked each time the BSC is used. The effectiveness of the biosafety cabinet is directly dependent on the manner in which users perform their work.

The effectiveness of the cabinet is a function of three separate directional airflows.

1. Inward airflow from the room through the front grille provides personal protection.
2. Downward airflow through a HEPA filter onto the work surface provides product protection.
3. Airflow out of the cabinet through an exhaust HEPA filter provides environmental protection.



Using the BSC

1. It is good microbiological practice to wipe down the cabinet work surface with disinfectant before beginning work.
2. Supplies needed for work should be placed into the cabinet and the cabinet allowed to run for 10 -15 minutes to establish proper airflow.
3. The vertical sash is kept below the indicated calibrated height.
4. Avoid creating turbulence in the cabinet by only placing those supplies needed for the experiment into the cabinet.
5. The work area should be set up with a workflow pattern of clean to dirty.
6. All air grates are kept clear, including the front and sides.
7. When work is finished, wipe down all surfaces with disinfectant.
8. If the BSC is not being used, keep the vertical sash down and shut the blower off.
9. Be sure to turn the blower back on, decontaminate and run for at least 10 minutes before resuming use.
10. Most biosafety cabinets use recirculated airflow; therefore hazardous chemicals cannot be used within them. A hard ducted biosafety cabinet may be appropriate for hazardous chemical use, however spark potential from the motor is still a concern for use with flammable material. No biosafety cabinets at TetraGenetics are hard ducted.

Turbulence in the BSC

Turbulence may cause aerosols which can cross-contaminate open vessels or escape the cabinet and potentially cause exposure. Turbulence can be caused by various factors:

1. Blocking air flow grilles.
2. Air current eddies caused by heat from Bunsen burners or other heat sources. (Bunsen burners should not be used in a BSC.
3. Rapid movement of arms into or out of the cabinet.
4. Rapid movement behind the worker and across the face of the cabinet.

5. Down drafts from ventilation systems. BSCs should be located in areas away from ventilation intakes for this reason.
6. Cross drafts from opening doors near the BSC.

Air Flow

HEPA filters protect against particulates. Some BSCs have a digital gauge that monitors the performance of the filter and must read between within the manufacturer's specified range. If the reading falls below this range, notify the BSO so the filter can be replaced.

All BSCs at TetraGenetics are recirculated air; no cabinets are hard ducted to roof exhaust. Therefore, use of hazardous chemicals is prohibited within the cabinet.

Motors and lights are not explosion proof, so flammables should not be used.

If the BSC alarm goes off, cap any tubes quickly and close the sash. Contact the Biosafety Officer for evaluation. Post the door with a "Do Not Enter" sign.

Other BSC Considerations

Nothing can be stored on top of the cabinet.

A biohazard label is posted on each BSC.

Sharps Containers

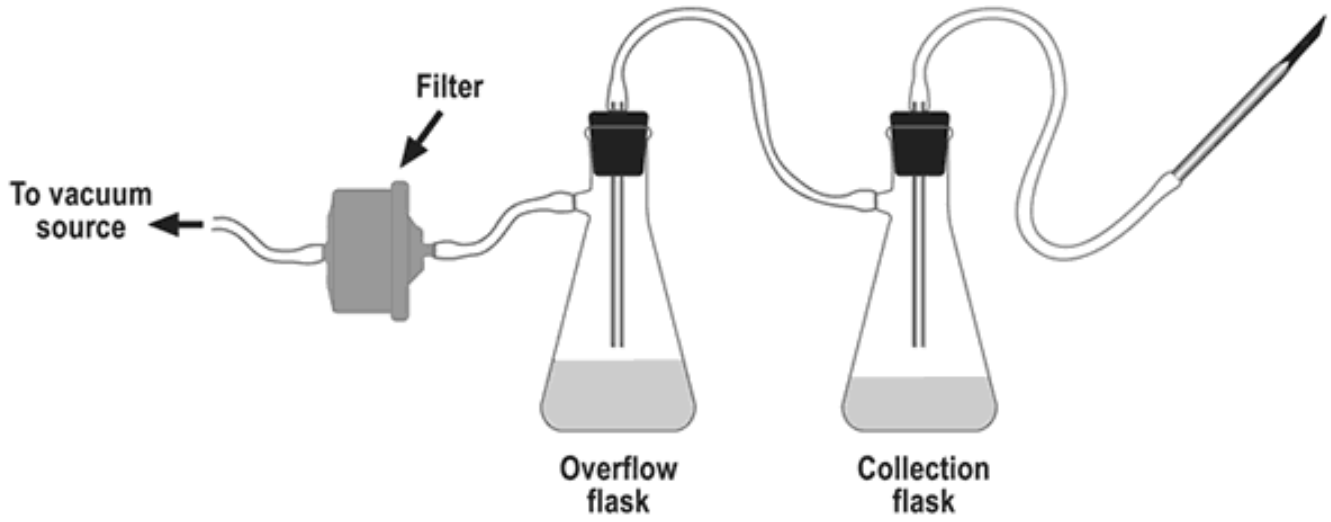
Sharps containers are made of puncture resistant material, typically polypropylene or plastic. Containers are examined and maintained after each procedure to ensure they are not compromised. When a container is full it is sealed and brought to the waste storage room by the Biosafety Officer. A new container is then put into service.

Aspiration Filters

Aspiration units used with Risk Group 2 or higher materials must be fitted with and in-line HEPA filter. This filter protects the house vacuum system, or pump, from potential contamination. The filter is checked before each procedure.

Aspiration Guideline

Protecting the vacuum line is one of the goals of proper aspiration set-up. The vacushield or other in-line filter, reduces risk of contaminating the in-house vacuum. The second line of defense is the overflow flask which is set up behind the primary collection flask. See the figure below for proper set-up, showing locations of the primary collection flask, the overflow flask, and the in-line filter.



Aspiration Work Practices

Always pre-measure disinfectant and add it to the collection flask before beginning work so that waste is disinfected as it is collected. Label the flask accordingly with biohazard waste and disinfectant name. Change the disinfectant daily, as appropriate.

If the collection and overflow flasks are on the floor, protect against breakage and use secondary containment to catch any spills.

When removing the stopper from the collection flask, work in the Biosafety Cabinet to prevent exposure from aerosols generated by splatter or splash.

Plexiglass Shielding

Plexi shielding, either in the form of a faceshield or a bench shield is used to provide protection from splash or splatter when working with materials outside of a BSC. Biohazardous work done on a bench instead of in a BSC must be reviewed and assessed by the Biosafety Officer prior to the initiation of work.

Plexi shields are examined and disinfected after each procedure.

9. WORK PRACTICES

Universal Precautions

When human source materials are used universal precautions must be adhered to. "Universal precautions" means treating material as if it is potentially infectious. When using universal precautions, one performs tasks using practices to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids are considered to be potentially infectious materials.

Non-Human Primate (NHP) Material

Due to the close genetic relationship between humans and NHP, which may lead to a greater occurrence of zoonosis, all work with NHP tissues must be handled at BL2. NHP material from Macaques may be contaminated with Herpes B Virus (aka B Virus). This potentially lethal zoonotic disease may be present in asymptomatic animals, and positive animals often do not present with circulating antibodies. For these reasons, all NHP material are handled at BL2 under universal precautions reasoning. Work with NHP material that is known to contain B Virus must undergo a full risk assessment and may be handled at a higher biosafety level. Exposures to NHP material must be cleaned immediately and medical advice sought.

There is currently no work with NHP material at TetraGenetics and there are no plans at this time to conduct NHP work in the future.

Minimum Requirements for Work in a Biological Lab

1. Hands are washed immediately, or as soon as feasible, after removal of gloves or other personal protective equipment. Hand washing sinks are located in each laboratory.
2. Following contact with blood or other potentially infectious materials, hands and any other skin are washed with soap and water.
3. Contaminated needles and other contaminated "sharps" are not to be bent, sheared or broken.
4. Needle recapping is not permitted when working with human blood, body fluids or tissue. If recapping is absolutely necessary, perform a risk assessment, and use single handed recapping devices. Never bend, break, or sheer a needle. Never remove a needle from a syringe; dispose as a unit.
5. Immediately, or as soon as possible after use, contaminated sharps must be placed in puncture-resistant, labeled, leakproof containers. Sharps containers are located at each employee's lab bench. Full sharps containers are removed by the lab employee and placed in the waste room. The medical/biohazardous waste is then shipped out for processing by a licensed medical waste transporter. The current medical waste transporter is Veolia Environmental Services.
6. Eating, drinking, smoking, applying cosmetics, and handling contact lenses are prohibited in all lab work areas.
7. Food and drink are prohibited from lab and work areas including refrigerators, freezers, shelves, cabinets, countertops, and benchtops.

8. Avoid hand contact with your mouth, nose and eyes.
9. Protect wounds and dermatitis with bandages and gloves, and double glove.
10. All procedures involving blood, or other potentially infectious materials, are performed in a manner that minimizes splashing, spraying, spattering, and generation of droplets of these substances. The following procedures have this potential and methods which will minimize these risks are given.
    a. Transfer liquid samples between containers in the biological safety cabinet or behind a benchtop safety shield.
    b. Centrifuge liquid samples in tightly closed bottles, within covered centrifuge rotors, within covered centrifuges. Allow to settle for 10 minutes prior to opening on the bench or open in a biological safety cabinet.
    c. Concentrate liquid samples under nitrogen pressure behind benchtop safety shields. The pressure release valve is covered with absorbent materials during pressure release.
    d. When vortexing liquid samples, use test tube caps to cover samples. Place gauze around cap before opening.
    e. When aspirating liquid samples, use an overflow flask and a HEPA filter for protection of vacuum lines. Remove stopper from waste flask in the biosafety cabinet.
11. Mouth pipetting is absolutely prohibited.
12. Specimens of blood or other potentially infectious materials are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping. The container is closed prior to storing, transporting, or shipping. Specimens are labeled with the Universal Biohazard Symbol prior to transport from one location to another, both within and outside the facility. All packaging and shipping is in accordance with federal regulations.
13. If outside contamination of the primary container occurs, the primary container is placed within a secondary container that prevents leakage during handling, processing, storage, transport, or shipping. If a specimen could puncture the primary container, the primary container is then placed within a secondary puncture-resistant container. Secondary containers are located in the lab areas and include closable, leakproof plasticware such as Tupperware® or Rubbermaid® containers.
14. All equipment which may become contaminated with blood, or other potentially infectious materials, is examined by the employee prior to servicing or shipping and is decontaminated, as necessary, using standard disinfection methods. Appendix 7 outlines the schedule and process of equipment decontamination. If decontamination of the equipment or portions of such equipment is not feasible, a readily observable label with the Universal Biohazard Symbol is attached to the equipment stating which portions remain contaminated. This information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate prior to handling, servicing, or shipping so that the appropriate precautions are taken.

15. The use of sharps in the laboratory should be avoided as much as possible. Double edged razors are forbidden in the lab. If razors or scalpels are needed, sheaths must be used to cover the sharps when not in use. Box cutters should be used for opening packages and for cutting, when possible. If needles are used, they are never recapped, bent, sheared or broken. All needle/syringes are disposed as a unit; needles are not removed from a syringe before disposal. ALL sharps are disposed into a puncture resistant sharps container. Any sharps work with BL2 materials requires prior notification to the Biosafety Officer and documented training.
16. Substitute plastic for glass whenever possible in the lab. This reduces the sharps exposure risk.

Personal Protective Equipment (PPE)

Personal protective equipment is provided by the supervisor at no cost to the employee when there is potential for occupational exposure to biohazards. Appropriate personal protective equipment may consist of, but is not limited to, gloves, lab coats, gowns, eye protection, masks and faceshields. All personal protective equipment is to be readily accessible and available in the appropriate sizes.

Personal protective equipment will be available in the Main BL 1 Laboratory and in the BL2 Tissue Culture Room. The Biosafety Officer will ensure that the necessary equipment and clothing are available in these locations.

It is the employee's responsibility, when there is occupational exposure or the potential for exposure, to use the appropriate personal protective equipment and clothing.

General PPE guidelines

PPE guidelines apply to all labs, glasswash and media prep areas.

1. No open toed shoes or sandals are worn in the laboratory areas.
2. Personal attire that does not cover the entire leg area is discouraged. If shorts are worn, a lab coat must be used, even in those labs not requiring the use of a lab coat (BL1).
3. Only low allergen, unpowdered non-latex gloves are used in the laboratories.
4. Protective eyewear will be worn in all labs.
5. PPE must not be worn out of the laboratory areas. Office areas and carpeted areas throughout the building are off limits for PPE.
6. **Never touch doorknobs with gloves, even if they are clean gloves!** This will lessen the chance of the spread of contamination.
7. If transporting material on a cart, do not touch the cart handle with gloves. Keep a box of gloves on the cart to use when touching the material.
8. Never transport or consume food or drink in the lab space. Lab space includes the laboratories themselves and the lab hallways.

BL1 PPE REQUIREMENTS

Required PPE: Safety glasses; face shields for cryogenic work

Recommended PPE: Lab coats, gloves; goggles when splashes or splatters can occur

BL2 PPE REQUIREMENTS

Required PPE: Safety glasses, buttoned lab coats, gloves; face shields for cryogenic work
Recommended PPE: Face shields and goggles when splashes or splatters can occur

Personal protective garments that are contaminated are to be removed immediately, or as soon as feasible, and prior to leaving the work area. Unsoiled lab coats are removed and left in the work area prior to leaving the area. All lab coats will be laundered weekly. Disposable lab coats are placed in the biohazardous waste container.

Gloves are worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; and when handling or touching contaminated items or surfaces. Gloves are worn for all procedures involving blood, samples derived from blood, and other human materials. Gloves, of the appropriate type, are also worn when working with chemicals.

Disposable gloves are replaced as soon as practical when contaminated; or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised. Gloves are disposed of in the biohazardous waste containers located in the laboratory areas, and should not be placed in regular trash. Gloves are removed immediately after visible contamination and before leaving the work area.

Disposable gloves are not washed or decontaminated for reuse. Utility gloves (i.e. rubber household gloves) for housekeeping chores involving potential blood contact and for instrument cleaning and decontamination procedures may be used. Utility gloves may be decontaminated and re-used, but should be discarded if they are peeling, cracked, or discolored, if they have punctures or other evidence of deterioration, or if their ability to function as a barrier is compromised.

Safety glasses are required of all personnel in all laboratory areas. Chin-length face shields are worn whenever splashes, spray, splatter, aerosols or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated. Faceshields are disinfected when contaminated or disposed of in the biohazardous waste container. Non-contaminated face shields remain in the work area for future use.

Housekeeping

The worksite is maintained in a clean and sanitary condition according to a written schedule for cleaning and use of the proper methods of decontamination. The schedule and methods are based upon the location of the worksite within the facility, the type of surface to be cleaned, the type of soil present, and the tasks or procedures being performed in that area. The written schedule is located in Appendix 7**.**

All equipment and working surfaces are to be cleaned and decontaminated after contact with

blood or other potentially infectious materials. Contaminated work surfaces are to be decontaminated with an appropriate disinfectant:

1. After completion of procedures.
2. Immediately or as soon as feasible when surfaces are overtly contaminated.
3. After any spill of blood or other potentially infectious materials.
4. At the end of the work day.

Protective coverings used to cover equipment and surfaces are removed and replaced as soon as feasible when they become contaminated. Bench paper with impermeable plastic backing or washable trays may be used to protect benchtop surfaces from contamination. If bench paper is used, once the paper is contaminated it is disposed of in the biohazardous waste container. Coverings are replaced on an as-needed basis or per the schedule in Appendix 7.

All reusable bins, pails, cans and similar receptacles, which have a reasonable likelihood of becoming contaminated with blood or other potentially infectious materials, are inspected and decontaminated on a regular basis as well as being cleaned and decontaminated immediately, or as soon as feasible, upon visible contamination. All biohazardous waste containers will be monitored, by the Biosafety Officer, at least weekly. If contaminated or found to be leaking, they will be decontaminated and replaced, if necessary.

Disposal of all regulated waste is in accordance with the Massachusetts State Sanitary Code (105 CMR 480.000) and the waste disposal policies of TetraGenetics.

Safer Sharps

TetraGenetics must institute a safer sharps program for all employees that use sharps with human materials or OPIM. Since no one device will be appropriate or effective for all circumstances, employers must select devices that are based on reasonable judgment, such as

1. The sharp will not jeopardize employee safety or be medically inadvisable;
2. The sharp will make an exposure incident involving a contaminated sharp less likely to occur.

Employers must solicit input from those non-managerial employees responsible for the use of engineered controls regarding the identification, evaluation, and selection of those controls, including safer medical devices. The sharps evaluation form is located in Appendix 8. The employees selected should represent the range of exposure situations encountered in the workplace, such as those in research, safety, support staff, and others involved in the direct use of sharps.

Note: During inspections, OSHA will check for compliance with this provision by questioning a representative number of employees to determine if and how their input was requested.

Signs and Labels

Warning labels are affixed to containers of regulated biomedical waste, such as liquid or semi-liquid blood and other potentially infectious materials; refrigerators and freezers containing BL2

materials, blood or other potentially infectious materials; equipment used to manipulate BL2 materials, blood, or other potentially infectious materials; and other containers or storage areas used to collect, transport or ship this material. The biohazard symbol required by this standard is fluorescent orange or orange-red, with lettering or symbols in a contrasting color.

The required labels will be affixed as close as feasible to the container by string, wire, adhesive or any other method that would prevent their unintentional loss or removal.

Red bags must be used for the collection of biological waste. These bags must be marked with the universal biohazard symbol or the word "biohazard" in a contrasting color. Contaminated equipment should be labeled as to which part of the equipment is contaminated. Regulated waste that has been decontaminated does not have to be labeled.

Shipping

Shipping, transport and receipt of biological materials can be a complex matter if dealing with infectious or potentially infectious substances. The World Health Organization offers information for shipment of biological materials at http://www.who.int/ihr/publications/who_hse_ihr_20100801_en.pdf. Appendix 9 lists various resources available to contact with questions about receipt and transport of regulated materials.

All biological shipments must conform to the Department of Transportation (DOT) and International Air Transport Association (IATA) requirements, as appropriate. Appendix 10 outlines such requirements for packaging and labeling of infectious materials and clinical specimen containers and can be used as guidance for preparing packages for shipment. However, any employee involved in packing, shipping, or signing manifests for these items must have DOT and IATA training as appropriate.

Cryogenics

Work with liquid nitrogen has potential safety hazards. If personnel are working with liquid nitrogen, which includes filling dewars or removing samples from deep freeze, the following precautions must be followed:

1. Work is done using a faceshield.
2. Cryo gloves are used when handling liquid nitrogen.
3. Employees do not change-out liquid nitrogen tanks unless trained to do so.

Children in the Lab

Children under the age of 18 are not allowed in laboratories.

10. DECONTAMINATION

Laboratories are subject to contamination by infectious and non-infectious biological material. Frequent decontamination is necessary to 1) provide a work area that is suitable for good microbiological practices and 2) render contaminated material safe for handling.

There are three types of decontamination:

1. Sterilization
2. Disinfection
3. Antisepsis

Sterilization

Sterilization refers to the destruction of all forms of life on a particular item or in a particular area. Sterilization may be accomplished using steam or gas, (e.g. steam sterilizers or ethylene oxide autoclaves), radiation (e.g. ^{60}Co) or a liquid (e.g. glutaraldehyde, under certain conditions). Sterilization is used to process clean, prewrapped items in which the steam or gas can penetrate to reach all areas within the packaging. Sterilization is also used for liquids, like culture media, to ensure biological experiments are accurate. The use of sterile equipment, media, and techniques prevents unwanted microorganisms from contaminating cultures.

Most equipment, media, and sometimes waste materials, are sterilized in the steam autoclave. The autoclave can be used at various cycle lengths for different purposes. For example, the cycle time for dry goods sterilization will be shorter than for a liquid with a high protein load. As protein load increases, so does the cycle time for sterilization. Appendix 11 is a guide to autoclave use and safety.

Ethylene oxide sterilizers are also commonly used; usually in the healthcare industry for implants and other medical equipment. Ethylene oxide is a toxic gas and regulated by OSHA. There are guidelines in place to use ethylene oxide sterilizers safely and to keep exposure below the OSHA Permissible Exposure Limit.

Disinfection

Disinfection is the process of using antimicrobial agents on inanimate objects to destroy a large proportion (99.999%) of non-spore forming organisms that could pose a hazard to humans or compromise an experiment. Usually disinfection is performed with a chemical agent, but heat can also be a type of disinfection treatment for liquid materials.

There are many types of chemical disinfectants used in laboratories:

1. Chlorine based compounds, usually sodium hypochlorite solution (Bleach)
2. Alcohols, typically ethanol or isopropanol
3. Glutaraldehyde solutions
4. Iodophors, such as iodine
5. Phenol based solutions

6. Quaternary ammonium compounds

There is no universal disinfectant for all microbial agents. Some disinfectants are useful against many different types of microbes, others are used for very specific situations and agents. Various hazards exist for each type of chemical disinfectant. A risk assessment is performed for all agents in use to determine which disinfectant is effective against the agent in question, under the conditions found in the lab or in the given solution, at the lowest hazard to the individual using it. Appendix 12 gives a broad overview of common chemical disinfectants and the types of microbe that each is effective against as well as the hazards associated with each.

Disinfectants for Work Surfaces and Reusable Items at TetraGenetics

The following disinfectants are acceptable for work surfaces and reusable items at the prescribed concentrations:

1. 10% solution of bleach. The shelf life of diluted bleach is only a few hours, so bleach should be diluted fresh immediately before use, or daily at a minimum.
2. 70% solution of ethyl or isopropyl alcohols. The shelf life of diluted alcohol is about a month.

Disinfectants for Waste at TetraGenetics

The following disinfectants are approved for liquid waste decontamination at the prescribed concentrations:

1. Bleach to a final concentration of 10% in liquid waste. This disinfectant is best for human source materials. If the protein load is high in the liquid waste that is being disinfected, a 20% final concentration is necessary.

See section 11, Regulated Waste, for specific procedures.

Disinfectants for Spill Clean-up at TetraGenetics

For all spill cleanup, a fresh solution of 10 to 20% bleach should be prepared. A 70% ethanol rinse solution can follow bleach when cleaning up a spill. Do not, under any circumstances substitute methanol for this step. Methanol and bleach form an incompatible mixture, which can be potentially explosive. Approximately twice the volume of disinfectant to the volume of the spill should be used. See section 15, Emergency Procedures, for more guidance on spill cleanup.

Antisepsis

Antisepsis is the application of a liquid chemical antimicrobial agent to living human or animal tissue. This chemical agent is intended to inhibit or destroy the growth of potentially infectious organisms. Handwashing with antimicrobial soap after exposure to a biological material is an example of antisepsis.

11. REGULATED WASTE

Sharps
Needles, scalpels, glass Pasteur pipettes, broken glassware, and any other material which would puncture biohazard bags are placed in a puncture resistant, rigid receptacle. All sharps containers are red in color and labeled with the Universal Biohazard Symbol.

Red Bag Medical Waste
Dry waste that is contaminated with biohazardous material is considered red bag waste. This includes all paper, plastic, petri dish cultures, test tubes and conical tubes. No loose sharps are allowed in red bag waste and only a very limited quantity of liquid is allowed. Trace chemotherapy agent waste is allowed in red bag waste, however these boxes must be labeled for incineration only. Full, sealed disposable bench-top sharps containers may be disposed of in red bag waste. All red bag waste is placed in a double-bagged cardboard receptacle with the Universal Biohazard Symbol on it. Plastic, flip top lids are required on the boxes in the BL2 lab.

Liquid Waste
For liquid waste decontamination, use the following concentration of disinfectant and allow for 30 minutes of contact time prior to sink disposal:

1. Bleach: 10% final concentration in liquid waste (sodium hypochlorite solution). This disinfectant is best for human source materials. For waste that has a high organic load, a 20% concentration of bleach is necessary.
2. To disinfect waste properly, a 30 minute contact time is necessary for all liquids prior to sink disposal.

Liquid waste containing no chemical components may also be autoclaved prior to sink disposal. Each cycle and its parameters must be recorded in the biological waste log book. Quarterly challenge testing must be performed, and maintenance records kept for the autoclave.

All in-house methods of waste treatment must be approved by the IBC. The biological waste log must be filled out for both solid and liquid waste (collected in batch), to be in compliance with the MA sanitary code 105 CMR 480.000.

Glass
Non-hazardous, non-contaminated intact and broken glass can be placed in cardboard containers labeled as "CLEAN, BROKEN GLASS DISPOSAL". Broken glassware is not to be picked up directly with the hands. Long forceps or dustpan/scrapers are utilized and these items must be decontaminated after use. **NO BIOHAZARDOUS AGENTS** are allowed in these containers.

Regular Trash
No biohazards, chemicals, broken glass, sharps, or gloves are allowed in the regular trash receptacles.

12. TRAINING

General Biosafety

Supervisors are to ensure that employees with occupational exposure to biological material participate in a training program that is provided at no cost to the employee. Employees are to complete the training at the time of initial assignment to tasks where occupational exposure may take place, or when there is a change in an employee's responsibilities, procedures, or work situations which places them at risk of such exposure, and at least annually thereafter.

Annual training will be carried out by the Biosafety Officer or Safety Consultant**.**

Training aids will consist of power-point slides, copies of in-house policies and other written materials to supplement the training.

Training materials are located in the central safety files located in the main lab.

Training records are maintained by the Biosafety Officer**.**

Copies of all policies and procedures as outlined in this manual are provided to each affected employee.

Bloodborne Pathogens

All employees working with human source materials or OPIM must receive training on Bloodborne Pathogens, including specifics of Hepatitis B, HIV and Hepatitis C upon employment or assignment to tasks involving the potential for occupational exposure.

OSHA requires annual retraining.

The specifics of Bloodborne Pathogens Training is given in Appendix 13.

Training Records

All training sessions are documented in writing with training records kept in the central safety files which are located in the main lab by TetraGenetics for at least 3 years from the date of the training. The training record includes dates of training sessions, content of training sessions, names of persons conducting training sessions, and the name, signatures and job titles of all persons attending training sessions.

Medical Records

Confidential medical records for employees with occupational exposure are kept by Mount Auburn Occupational Health Serviced for the duration of their employment plus 30 years. Medical records include:

1. Employee's name and social security number
2. Employee's hepatitis B vaccination status, including vaccination dates and any medical records related to the employee's ability to receive vaccination
3. Results of examinations, medical testing, post-exposure evaluation and follow-up procedures
4. Written opinions of healthcare professionals
5. Copies of information provided to healthcare professionals

Sharps Injury Log

The sharps injury log will be maintained in a manner that protects the privacy of employees. At a minimum, the log will contain the date and time of the incident, the type and brand of device involved in the incident, location of the incident, and description of the incident. The Sharps injury log is contained in Appendix 14.

Safer Sharps Program

The Needlestick Prevention Act and Bloodborne Pathogens Standard require employers to evaluate safer sharps when used with human source materials (see section 10, Work Practices, for details of the program). The Safer Sharps Program will be documented with employee questionnaires and by physically evaluating newly engineered products on the market. The employer will provide the employee with the safest sharp appropriate for the job function at no cost to them.

13. MEDICAL SURVEILLANCE AND VACCINATIONS

Occupational Health Center
Mount Auburn Occupational Health Services makes the Hepatitis B vaccination series available to all employees who may potentially have occupational exposure, and extends post-exposure evaluation and follow-up to all employees who have had an exposure incident.

All medical evaluations and procedures, including the Hepatitis B vaccine and vaccination series, post-exposure evaluation and follow-up, and prophylaxis, are made available at no cost to the employee.

Hepatitis B Vaccination
The Hepatitis B vaccination form is given in Appendix 15. All employees with anticipated exposure to blood, tissue or other OPIM must accept or decline the vaccine and sign the form.

Employees receiving the Hepatitis B vaccine will follow procedures as outlined and required by Mount Auburn Occupational Health Services.

The vaccination series is administered by a nurse or practitioner at Mount Auburn Occupational Health Services. The vaccination is safe and effective and given as a 3 shot series at no cost to the employee.

The Biosafety Officer has the responsibility to ensure that the vaccination is offered within 10 days of the employee falling under the bloodborne pathogen standard, and declinations are documented appropriately.

Post-Exposure Evaluation and Follow-Up
Mount Auburn Occupational Health Services will provide post-exposure evaluation, treatment, and follow-up, after the report of an exposure incident.

All exposures will be reported immediately to the supervisor and the Biological Safety Officer. In addition, an incident report must be filled out within 24 hours. Appendix 16 is the Incident Report for Occupational Exposure to Human Materials or OPIM.

The employee will wash the exposed area thoroughly with soap and water and will be transported by car or ambulance to Occupational Health Center or Emergency Room for evaluation and treatment of the exposure.

A healthcare professional's written opinion may be obtained in the following situations: 1) when employee is sent to obtain the Hepatitis B vaccine, 2) whenever the employee is sent to a healthcare professional following an exposure incident. Written opinions will follow Mount Auburn Occupational Health Services policy.

All medical records relating to post-exposure evaluation and follow-up are confidential.

Mount Auburn Occupational Health Services will monitor post-exposure policy effectiveness and maintain records related to this policy.

Serum Storage Medical Surveillance

Occupational Health will provide serum storage for those employees designated for medical surveillance. This may be required as part of a recombinant DNA registration or for those employees working at BL2 Enhanced containment with viral agents. Mount Auburn Occupational Health Services can be contacted to evaluate situations that may warrant serum storage.

14. EMERGENCY RESPONSE

It is important to summon help immediately in the event of a medical emergency or life threatening exposure incident. For any emergency that is life threatening:

1. Yell "help" to get another person to aid in the situation
2. Dial 911 to get immediate help from emergency responders

All emergencies are reported immediately to the supervisor. Biological exposure emergencies are reported to the Biological Safety Officer as well.

Resource Information

Red emergency binders include information on emergency response, evacuation response and biological spill response, among other things. The red binder should be used if there is an emergency and immediate action must be taken.

An emergency phone list is posted by all laboratory phones. The list includes the contact information for various emergency services, including:

1. Hospital emergency room information
2. Occupational Health contact and fax numbers
3. Emergency Coordinator contact information
4. Safety Officer contact information
5. Safety consultant contact information, if applicable
6. Spill contractor information

Exposure Response

Immediate response to a biological exposure is necessary to prevent possible infection.
If an exposure to a biological material occurs, it is important to identify the material immediately and obtain a sample for evaluation if it has not been previously tested. If testing data is available in the safety records or from the supplier, obtain the results immediately.

In general, follow the guidelines below for immediate response to biological exposure:

Eye Splash:	Hold eye open at eyewash station and rinse for 15 minutes
Needlestick:	Use soap and wash exposed area for 15 minutes in a lab sink. Report immediately and go to Occupational Health or the ER for consultation.
Skin Exposure:	Use soap and wash exposed area for 15 minutes in a lab sink or safety shower.
Open Wound Exposure:	Massage and apply gentle pressure to force bleed cut. Rinse well with clean water and continue to force bleed cut.
Mucous Membrane Exposure:	Rinse area, to the best of your ability, with clean water.
Exposure to Clothing:	Remove clothing that has been contaminated and if material soaked through to the skin, wash exposed skin as explained above.

All overt exposures from parenteral inoculation and/or exposure to mucous membranes **MUST** be reported immediately to the supervisor and biological safety officer. Medical attention must be promptly sought for any exposures of this type, but especially for exposures to human source materials. Counseling regarding the risk of infection should be given by a medical professional, either at the emergency room, or Occupational Health Center.

All exposures are reported on an incident report form with 24 hours of the incident. Incident report forms can be found in the last section of the emergency binder and in the safety folder on the network.

It may be suggested by the medical professional to obtain a Hepatitis B vaccination or prophylaxis following exposure to human source materials. It may also be suggested to begin a drug regimen to minimize the chance of HIV seroconversion, which must be given within a short time after exposure to known HIV positive material. A medical professional must be consulted as soon as possible after exposure to counsel the exposed employee appropriately.

Spills

Spill supplies for biological spill cleanup can be found in the Main Laboratory by the handwash sink and BL2 Tissue Culture Room. Supplies for biological spills include the following:

1. At least 1 gallon of bleach. Periodically check the date on all bleach bottles to be used for spill cleanup to ensure that they are not expired.
2. Paper towels, or other absorbents
3. PPE shall be available in the lab, such as a lab coat, gloves, and face shield or goggles.
4. Biohazard bags to contain spill materials.
5. Forceps or a dust pan and broom to pick up contaminated sharps items, such as needles, broken glass or broken, rigid plastic items.

Containing biological spills, and especially aerosols produced by a spill, is extremely important to the safety of individuals cleaning a spill. Precautions must be taken to avoid spreading contamination while performing biological spill cleanup. All waste produced from the cleanup must be disposed of as biological hazardous waste.

Spills of BL1 Materials

1. Wash hands and exposed skin immediately if you have been exposed to the spill.
2. Personal Protective Equipment (PPE) must be worn during spill cleanup. A lab coat, safety glasses, and gloves are required. Booties, goggles and face shields should be used as necessary, depending on the volume of the spill and the possibility for splash, splatter or formation of aerosols.
3. Assemble the spill kit materials before attempting spill cleanup.
4. Surround the spill with bleach so that the disinfectant can be mixed into the spill using paper towels. A ring of bleach around the spill will keep the spill from spreading.
5. Place absorbent materials, like paper towels, over the spill once the disinfectant has been mixed into the spill.
6. Add bleach over the paper towels to produce an estimated volume to volume concentration

of 1:10, bleach to spill ratio.
7. Allow contact time of at least 30 minutes for disinfection of the spill.
8. Wipe up the spill and dispose of used clean-up materials in the biohazardous waste containers.
9. Dispose of any sharps into puncture resistance "sharps" containers. Never pick up sharps with your hands; use a dustpan and broom or tongs to handle sharps.
10. Clean the spill area with a soapy solution after all materials have been picked up and placed in the appropriate waste containers. This step is necessary to remove any protein substances left on surfaces from the spill.
11. Clean the area one more time with a freshly prepared 10% bleach solution. A 10% bleach solution can be prepared by adding 100ml of regular household bleach to 900ml of water. If using industrial strength bleach, read the label and dilute accordingly to a final concentration of 5,000 ppm chlorine. (Most household bleach is 52,500 ppm chlorine).
12. Follow with a final rinse of water or 70% ethanol to remove bleach residue.
13. Reusable items used in spill cleanup must be disinfected or autoclaved prior to returning to the biological spill kit location.

Spills of BL2 Materials

For spills of BL2 materials, or any BL1 spill that may produce aerosols, use the above listed BL1 spill procedures plus:

1. Leave the lab quickly and evacuate all personnel from the lab. Close the door and post a "no entry" sign.
2. Put any contaminated lab coats and clothing in a red biohazard bag before leaving the lab if it is safe to do so. Seal the biohazard bag and label it with your name, date and identity of the contents. Contact the Biosafety Officer about the spill and potential contamination. Contaminated clothing will need to be autoclaved before being sent to the launderer.
3. Allow 30 minutes for aerosols to settle before reentering the lab and proceeding with clean-up.
4. Contact your Supervisor, Biosafety Officer and a Safety Team Member to discuss the logistics of clean-up.
5. Always wear personal protective equipment, including a lab coat, gloves and safety glasses. Booties, a face shield or goggles may be appropriate depending on the volume of the spill.
6. While cleaning the spill, avoid splashing or splattering the materials, which can produce aerosols.
7. Pour disinfectant, preferably bleach, in a ring around the spill to stop the spread of biological contamination. Let the disinfectant flow into the spill and use paper towels to mix the disinfectant into the spill. Make sure you include any areas where aerosols may have settled.
8. Place a layer of paper towels over the spill and pour disinfectant over the center of the towels. The paper towels will reduce any splash or splatter that may occur if you added the disinfectant directly into the spill.
9. Allow 20 to 30 minute contact time before wiping up gently. Remove any sharps or

broken glass by an indirect method, such as tongs, a dustpan and broom or a scoop. Any re-usable materials must be autoclave sterilized before returning to the spill kit.

10. Once the area is cleaned of the bulk of the biological spills, clean the area with a soap and water or detergent solution to break up any protein remaining on the surfaces. Follow this with a second application of disinfectant to ensure proper disinfection of the surfaces.

Spills in a Biosafety Cabinet (BSC)

The main protection from biological spills in a BSC is the HEPA filter. If there is a spill in the BSC, check the operation of the HEPA filter by looking at the magnehelix before attempting any spill cleanup. Make sure the magnehelix indicates that the filter is operating appropriately.

1. Put on clean gloves, a lab coat and safety glasses. Proceed with decontamination while the cabinet continues to run.
2. Spray down cabinet surfaces and equipment with the preferred disinfectant and wipe all surfaces. If using bleach, follow these procedures with a water or 70% ethanol rinse to reduce corrosion of the metal surfaces.
3. If possible, lift the front exhaust grille and tray, spray with disinfectant and wipe. If you cannot lift the front grill, flood the drain pan beneath the work surface with disinfectant and allow 20 - 30 minutes contact time before draining.
4. Call the Biosafety Officer if the spill is inaccessible or contaminates a filter.

Biological Mixed Spills

In general, biological mixed spills should be treated as follows: for biological and chemical spills use a disinfectant that is compatible with the spilled chemical to kill the biological material and then treat as chemical waste.

Consult the Safety Officer for all mixed spills.

15. GLOSSARY OF TERMS AND ACRONYMS

AMPHOTROPIC VIRUS: An RNA tumor virus, or oncovirus, that does not produce disease in its natural host, but does replicate in tissue culture cells of the host species and in cells from other species.

ANSI: American National Standards Institute

BIOSAFETY OFFICER: also known as Biological Safety Officer or BSO, oversees and gives safety input for all biological work done in the facility. See section 2 for site specific details.

BL: Biosafety Level

BLOOD: Human blood, blood components, and products derived from blood.

BLOODBORNE PATHOGENS: Pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).

BMBL: *Biosafety in the Microbiological and Biomedical Laboratory*

BSC: Biosafety cabinet

CDC: Centers for Disease Control

EBV: Epstein Barr Virus

ETIOLOGIC: Cause or origin of disease

EXPOSURE INCIDENT: A specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious or biohazardous material that results from the performance of an employee's duties.

HUMAN CELL LINE: An **in vitro** or animal-passaged culture or human cells that fulfill traditional requirements of a **cell line** designation. That is, the cells are **immortalized** cells, transformed by spontaneous mutation or natural or laboratory infection with an immortalizating agent such as Epstein-Barr virus (EBV). Note: EBV is a bloodborne pathogen.

HUMAN CELL STRAINS: Cells propagated **in vitro** from primary explants of human tissue or body fluids which have finite lifetime (non-transformed) in tissue culture for 20-70 passages. Human cell "strains" must be handled as potential biohazards unless characterized by testing to be free of bloodborne pathogens.

HYBRIDOMA CELL LINES: Immortalized cell lines created by fusion of primary cells with a continuous cell line.

MURINE: Relating to, affecting, resembling or derived from a rat or mouse.

NEEDLELESS SYSTEMS: Devices, for various procedures, that provide an alternative to needles and reduce the risk of injury involving contaminated sharps. Examples include:

1. IV medication systems which administer medication or fluids through a catheter port using non-needle connections; and
2. Jet injection systems which deliver liquid medication beneath the skin or through a muscle.

NIH: National Institutes of Health

OCCUPATIONAL EXPOSURE: Reasonably anticipated skin, eye, mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious or biohazardous material that may result from the performance of an employee's duties.

ONCOGENIC: Causing or tending to cause the formation and development of tumors.

ONCOVIRUS: An RNA tumor virus.

OTHER POTENTIALLY INFECTIOUS MATERIALS (OPIM):

1. Body fluids and secretions including semen, vaginal, cerebrospinal, synovial, pleural, pericardial, peritoneal, and amniotic; saliva in dental procedures, and any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids.
2. Any unfixed tissue or organ other than intact skin from a human, living or dead.
3. HIV-containing cell or tissue cultures, organ cultures, and HIV or HBV containing culture medium or other solutions; and blood, organs or other tissues from experimental animals infected with HIV or HBV.

PI: Principal investigator

POLYTROPIC VIRUS: Infectious for both murine and nonmurine cells.

RECOMBINANT DNA MOLECULES: Molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or the molecules that result from that replication.

REPLICATION COMPETENT VIRUS: Able to replicate or reproduce.

SAFETY COMMITTEE: An organizational structure where members represent all affected groups within the company to ensure that safety issues are addressed. This gives everyone a voice and should include an effective number of participants to address and enforce all issues.

SHARPS WITH ENGINEERED SHARPS INJURY PROTECTIONS: Non-needle sharps or needle/scalpel/knife devices which contain built-in safety features that are used for collecting fluids, administering medications or other fluids, or for other procedures that involve the risk of sharps injury. This description covers a broad array of devices, including:

1. Syringes with a sliding sheath that shields the attached needle after use;
2. Needles that retract into a syringe after use;
3. Shielded or retracting catheters;
4. Intravenous medication (IV) delivery systems that use a catheter port with a needle housed in a protective covering.
5. Retractable blade scalpel or Exacto knife

SOURCE INDIVIDUAL: Any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee.

UNIVERSAL PRECAUTIONS: An approach to infection control. All human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, HCV, and other bloodborne pathogens.

XENOTROPIC VIRUS: Also known as zenotropic virus. A virus that can grow in the cells of a species foreign to the normal host species, a species different from that which normally hosts it.

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APPENDIX 1 SUMMARY TABLE FOR BL1 – BL4

Table 2. Summary of Recommended Biosafety Levels for Infectious Agents

BSL	Agents	Practices	Primary Barriers and Safety Equipment	Facilities (Secondary Barriers)
1	Not known to consistently cause diseases in healthy adults	Standard microbiological practices	■ No primary barriers required. ■ PPE: laboratory coats and gloves; eye, face protection, as needed	Laboratory bench and sink required
2	Agents associated with human disease Routes of transmission include percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: ■ Limited access ■ Biohazard warning signs ■ "Sharps" precautions ■ Biosafety manual defining any needed waste decontamination or medical surveillance policies	Primary barriers: ■ BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials ■ PPE: Laboratory coats, gloves, face and eye protection, as needed	BSL-1 plus: ■ Autoclave available
3	Indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure	BSL-2 practice plus: ■ Controlled access ■ Decontamination of all waste ■ Decontamination of laboratory clothing before laundering	Primary barriers: ■ BSCs or other physical containment devices used for all open manipulations of agents ■ PPE: Protective laboratory clothing, gloves, face, eye and respiratory protection, as needed	BSL-2 plus: ■ Physical separation from access corridors ■ Self-closing, double-door access ■ Exhausted air not recirculated ■ Negative airflow into laboratory ■ Entry through airlock or anteroom ■ Hand washing sink near laboratory exit
4	Dangerous/exotic agents which post high individual risk of aerosol-transmitted laboratory infections that are frequently fatal, for which there are no vaccines or treatments Agents with a close or identical antigenic relationship to an agent requiring BSL-4 until data are available to redesignate the level Related agents with unknown risk of transmission	BSL-3 practices plus: ■ Clothing change before entering ■ Shower on exit ■ All material decontaminated on exit from facility	Primary barriers: ■ All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure suit	BSL-3 plus: ■ Separate building or isolated zone ■ Dedicated supply and exhaust, vacuum, and decontamination systems ■ Other requirements outlined in the text

Reference: *Biosafety in Microbiological and Biomedical Laboratories*, CDC/NIH

APPENDIX 2 PROCEDURES FOR BL2 ENHANCED

(There are no procedures requiring BL2 enhanced containment being conducted at TetraGenetics)

For work with agents that pose a moderate to high personnel risk AND a low to moderate environmental risk, the suitability of BL2 Enhanced containment is decided on a case-by-case basis. The control of potential biohazards is achieved by strict adherence to BL3 work practices and procedures in a BL2 facility. It is important that all personnel that work in BL2 Enhanced facilities understand and adhere to the proper procedures and techniques outlined in the project. The Institutional Biosafety Committee (IBC) must approve all BL2 Enhanced projects and the Biological Safety Officer must approve this BL2 Enhanced Biosafety Procedure. Failure to adhere to appropriate practices and procedures may endanger others. All personnel that work on a BL2 Enhanced project must be registered with the IBC and participate in medical surveillance programs as necessary.

A. STANDARD LABORATORY PRACTICES

1. Laboratory Access - Access is controlled by the Principal Investigator (PI) and is restricted to those persons whose presence is required for experimental or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may be unusually hazardous are not allowed in BL2 Enhanced laboratories or animal rooms. All equipment necessary for conducting experiments including centrifuges, incubators, waterbaths, etc., shall be kept in the BL2 Enhanced restricted access laboratory. The IBC must approve any exceptions. The PI establishes policies and procedures by which only persons advised of the potential hazards, which meet specific entry requirements, (e.g., immunizations), enter the laboratory or animal rooms. The PI has the final responsibility for assessing each circumstance and deciding who may enter or work in the laboratory.

2. Lower Containment Level Projects - Lower containment level projects may be carried out at the same time as BL2 Enhanced work, however, all personnel will follow BL2 ENHANCED practices and procedures.

3. Biohazard Sign - Post a universal biohazard sign with a BL2 Enhanced designation on the outside of the door to the laboratory. The warning sign identifies the infectious agent, lists the name and telephone number of the PI and other responsible person(s), and indicates the special requirements for entry into the laboratory.

4. Immunizations - Laboratory personnel receive appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing, etc.).

5. Sera storage - Baseline serum samples, as determined by the IBC, are collected and stored for all laboratory and other at-risk personnel. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the facility.

6. Biosafety Procedure / Manual - A biosafety manual is prepared or adopted. Personnel are advised of special hazards and are required to read and to follow instructions on practices and procedures.

7. Training - Laboratory personnel receive appropriate training on the potential hazards associated with the work, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural or policy changes. The Biological Safety Officer will review Standard Operating Procedures (SOP's) developed in conjunction with these BL2 Enhanced requirements. Training for ALL personnel in the area will be conducted, covering these requirements and the SOP's. Trained personnel will sign an attendance sheet, a copy of which will be maintained in the safety files, and with the PI.

    a. The PI is responsible for ensuring that, before working with organisms at BL2 Enhanced, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This may include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the PI or other competent scientist proficient in safe microbiological practices and techniques.

8. Work Practices - All manipulations involving BL2 Enhanced materials are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Minimize the generation of aerosols in experimental procedures. Load all centrifuge bottles, carriers, and tubes in the biosafety cabinet. Wipe outer surfaces with approved disinfectant before taking to centrifuge. Remove and replace gloves often. Do not use contaminated gloves to handle common equipment.

9. Sharps - Plasticware should be substituted for glassware whenever possible. Use of a hypodermic needle and syringe is to be avoided when alternate methods are available. Extreme care must be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels. Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles.

a. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of BL2 Enhanced materials. Used disposable needles must not be bent, sheared, broken recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

b. Syringes which re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate. Use remote capping systems; do not recap by hand.

c. Broken glassware must not be handled directly by hand, but removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass are decontaminated before disposal, according to any local, state, or federal regulations (see Section 13. Contaminated Wastes, below).

11. Packaging - Cultures, tissues, or specimens of body fluids are placed in two containers that prevent leakage during collection, handling, processing, storage, or intra-facility transport. For shipping materials to outside facilities, contact the Biological Safety Officer for shipping regulations and information on purchasing packing materials.

12. Decontamination - Laboratory equipment and work surfaces will be decontaminated with an appropriate disinfectant regularly; when work is completed, at the end of each workday, and especially after overt spills, splashes, or other contamination by BL2 Enhanced materials. Advice on decontamination is available from the Biological Safety Officer. Contaminated equipment must be decontaminated according to any local, state or federal regulations before it is sent for repair or maintenance or packaged for transport in accordance with applicable local, state, or federal regulations. Decontamination labels are affixed to equipment prior to shipping or removal from the lab to indicate that the equipment has been decontaminated.

    a. Autoclave - Any sterilization of BL2 Enhanced contaminated materials is done in an autoclave located within the building. Autoclaves must be tested periodically for proper temperature and pressure control as per State Sanitary Code. Validation with a biological indicator should be performed monthly, with results recorded in a logbook.

    b. If you find that an autoclave is not operating properly, please notify Facilities Management and your lab manager immediately.

13. Contaminated Wastes - BL2 Enhanced wastes and contaminated items will be decontaminated by the scientist before turning over to custodians or glasswash personnel. All liquid or solid wastes are decontaminated before disposal. Contaminated materials that are to be decontaminated away from the laboratory are placed in a durable leakproof container that is closed before being removed from the laboratory. Materials to be decontaminated off-site are packaged in accordance with applicable local, state, and federal regulations, before removal from the facility.

    a. Liquid Wastes - All liquid wastes generated during BL2 Enhanced experiments should be immediately decontaminated by mixing with bleach (10% final concentration) or equivalent disinfectant for at least 20 minutes contact time. The solution may then be disposed of in the sink; however, the sink must be washed and decontaminated after. Note: the State Sanitary Code requires documentation that the disinfectant is effective against the agent in use. Liquid radioactive wastes should be processed in accordance with established procedure.

    b. Non-Sharp Solid Wastes - Solid wastes contaminated with BL2 Enhanced materials must be autoclaved or incinerated. Solid waste containers shall consist of a double biohazard bag in a labeled, covered, autoclavable container. Before removal from the BL2 Enhanced facility, the bag should be sealed. If there is any possibility of a hole or tear in the bag, it should be autoclaved in the covered container. All biohazard bags containing BL2 Enhanced contaminated materials should be transported to the autoclave in a leakproof container. It is preferable to transport materials on a cart. Scientists are responsible for decontaminating this waste immediately after their experiment. Do not store the waste. Prior to autoclaving, open the bag or container slightly to allow for steam penetration. Once the solid waste is decontaminated, it may be tagged and treated as ordinary waste. Animal carcasses and cage materials should be processed according to established procedures such as incineration. Radioactive waste should be disposed in accordance with standard procedures.

    c. Sharp Waste - Sharp wastes contaminated with BL2 Enhanced materials will be collected as generated into labeled autoclavable puncture resistant containers. Cover before transporting to autoclave and autoclave for at least 30 minutes prior to disposal as laboratory sharps.

    d. Reusable Materials - Reusable materials such as non-disposable pipettes should be carefully submerged as used in a horizontal container filled with a suitable disinfectant. Care should be taken to fill items completely with solution and allow at least 20-minute contact time before washing.

14. Hand Wash - Persons wash their hands after they handle viable materials and animals after removing gloves, and before leaving the laboratory.

15. Pipetting - Pipetting by mouth is prohibited. Mechanical pipetting devices are to be used.

16. Food - Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the work area. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated and used for this purpose only.

17. Work Surfaces - Work surfaces shall be decontaminated daily and following spills of organisms.

    a. A bottle of disinfectant must be kept in every work area for spills on skin or work surface. All spills must be cleaned up immediately.

    b. At the end of every working day, all work surfaces including equipment used (e.g., centrifuges) are thoroughly wiped down with an appropriate decontaminant. See Appendix 12 for common disinfectants.

18. Insect and Rodent Control - An insect and rodent control program is provided. Call facilities to report any problems.

19. Accidents - Spills of biological materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious or potentially infectious material. Spills and accidents that result in overt exposures to BL2 Enhanced materials are immediately reported to the PI and Biological Safety Officer. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are kept.

    c. Spills in Biosafety Cabinet - Remove contaminated clothing and change gloves. Surround the spill with decontaminant solution. Cover with paper towels, and let mix for 20 minutes. Wipe down with a second application of disinfectant. Leave the cabinet fans on.

    d. Spills Outside Biosafety Cabinet - Evacuate the area, close the doors, and call the PI and BSO. Evaluate the spill by doing a risk analysis. Additional PPE may be required or recommended based on a spill evaluation. For splash and splatter hazards, a face shield is required. If aerosol route of infection is likely, a HEPA respirator or N95 mask may be used by a trained medically cleared and fit tested individual.

20. Animals and Plants - Animals and plants not involved in the experiment are not allowed in the laboratory.

B. SAFETY EQUIPMENT (PRIMARY BARRIERS)

1. Biosafety Cabinet (BSC) - Properly maintained BSCs (class II or III) are used for all manipulation of BL2 Enhanced materials (e.g., pipetting, dilutions, transfer operations, plating, framing, grinding, blending, drying, sonicating, shaking, centrifuging) except where equipment design provides for containment of the potential aerosol.

    a. Blenders - Use safety blenders that have been designed to contain aerosols.

    b. Centrifugation - Use pressure seal tubes/bottles secondarily sealed in centrifuge tube carriers. Load and seal in the BSC. Wipe down the outer surface with decontaminant before taking to centrifuge. If there has been any possibility of leakage, the inner walls of the centrifuge chamber and the rotor should be immediately decontaminated.

    c. Incubators - Use a dedicated BL2 Enhanced incubator with tight fitting plugs to seal openings. Membrane filter (0.22micron) tissue culture flasks in a secondary container may be used in shared incubators provided shelves, trays, and flasks are labeled clearly.

    d. Freezers/Refrigerators - Used for storage of BL2 Enhanced materials shall be signed with the universal biohazard symbol, and materials shall be enclosed in a clearly labeled, unbreakable secondary container.

    e. Labeling - All equipment where BL2 Enhanced materials are used in or stored in must be labeled with a universal biohazard symbol.

2. Personal Protective Equipment

    a. Lab Coats - Laboratory clothing that protects street clothing (e.g., long-sleeve solid-front or wraparound gowns, scrub suits, or overalls, no-button or slipover jackets) are worn in the laboratory. Front-button laboratory coats are unsuitable. Laboratory clothing may not be worn outside the laboratory. All lab coats must be autoclaved in a biohazard bag for one hour before laundering or discarding. Lab coats used repeatedly in BL2 Enhanced facilities should be processed once a week. Do not store overcoats, hats, etc. in the BL2 Enhanced area.

    b. Gloves - Wear gloves whenever handling infected animals, BL2 Enhanced materials, contaminated surfaces, or equipment. Double gloves may be appropriate; if a spill or splatter occurs, the hand will be protected after the contaminated glove is removed. Gloves are disposed of when contaminated, and replaced frequently during procedures. Do not wear contaminated gloves outside the work area. Keep common areas clean. Disposable gloves are not washed or reused.

c. Face Protection - Goggles, mask, faceshield or other splatter guards are used for anticipated splashes or sprays of infectious or other hazardous materials to the face, or when the microorganisms must be manipulated outside the BSC (e.g., harvesting of tissues or fluids from large infected animals).

d. Respiratory Protection - Respiratory protection is worn when aerosols cannot be safely contained (i.e. outside BSC - aerosol challenge of animals, necropsy of infected animals), and spill clean up outside of BSC.

Gilman 6/99

APPENDIX 3 ORDINANCE ARLINGTON rDNA ORDINANCE

SECTION 1: AUTHORITY

On April 11, 2012 the Arlington Board of Health, pursuant to the authority granted under Massachusetts General Laws (M.G.L.), Chapter 111, Section 31, voted to adopt the "**Biosafety and Recombinant DNA Regulations**" to protect the public health of the community.

SECTION 2: APPLICABILITY/ PURPOSE

These regulations shall apply to all research, production, and other associated activities involving rDNA materials or Biological Agents undertaken within the Town of Arlington, Massachusetts. All such activities shall be undertaken only in strict conformity with these regulations and with current National Institutes of Health (NIH) Guidelines (hereinafter referred to as the "Guidelines") as defined below herein § 3. Any institution engaged in research or production involving rDNA materials or Biological Agents shall also comply at all times with any other applicable federal and state regulations covering such work, including regulations promulgated by the Centers for Disease Control (CDC), Occupational Safety Health Administration (OSHA), Environmental Protection Agency (EPA) Massachusetts Department of Environmental Protection (MADEP) and Massachusetts Department of Public Health (MADPH).

These regulations are promulgated to ensure proper safe guards are in place for work with Biological Agents and recombinant DNA (rDNA) within the Town of Arlington. These regulations promote the safe and responsible conduct of science by institutions utilizing Biological Agents and rDNA materials, and promote competency and adequate training of laboratory staff in laboratory safety.

SECTION 3: DEFINITIONS

Biological agent: any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, or anything capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment. [from the CDC Select Agents and Toxins Final Rule. 42 CFR § 73.1 Definitions]

BMBL: Biosafety in Microbiological and Biomedical Laboratories. The key recommendations for working with biological materials in the United States (US) published jointly by the CDC and the NIH.

BSL: Biological safety level. There are four biosafety levels which consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facility containment. Each combination is specifically appropriate for the operations performed the documented or suspected routes of transmission of the infectious agents, and the laboratory function or activity.

Biosafety Level One Laboratory (BSL-1): All facilities that meet or exceed the criteria for Biosafety Level 1 containment, according to descriptions in the BMBL; appropriate for agents that are not known to cause disease in normal, healthy humans.

Biosafety Level Two Laboratory (BSL-2): All facilities that meet or exceed the criteria for Biosafety Level 2 containment, according to descriptions in the BMBL; appropriate for handling moderate-risk agents that cause human disease of varying severity by ingestion or through percutaneous or mucous membrane exposure.
Biosafety Level Three Laboratory (BSL-3): All facilities that meet or exceed the criteria for Biosafety Level 3 containment, according to descriptions in the BMBL; appropriate for agents with a known potential for aerosol transmission, for agents that may cause serious and potentially lethal infections and that are indigenous or exotic in origin
Biosafety Level Four Laboratory (BSL-4): All facilities that meet or exceed the criteria for Biosafety Level 4 containment, according to descriptions in the BMBL; appropriate for exotic agents that pose a high individual risk of life-threatening disease by infectious aerosols and for which no treatment is available
CDC: Centers for Disease Control and Prevention
EPA: Environmental Protection Agency
Guidelines: The most recent version of the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules published in the Federal Register, and any further amendments, wherever published, which are adopted by NIH, or any successor agency thereto.
In the event that the NIH shall abolish or discontinue its Guidelines, those Guidelines in effect at the time of such discontinuance shall remain in effect within the Town of Arlington until further written notice from the Board of Health.
Institution: Any single individual, group of individuals, or organization, whether public or private.
Institutional Biosafety Committee: (IBC) a committee established by an institution in accordance with the Guidelines and the terms set forth in these regulations
Large-scale: The use of more than ten liters of rDNA and/or Biological Agent culture. This threshold shall be based on the cumulative volume of culture in all vessels throughout the institution's facility, not just a single vessel or experiment.
MADEP: Massachusetts Department of Environmental Protection
MADPH: Massachusetts Department of Public Health
OSHA: Occupational Safety and Health Administration
Recombinant DNA molecules (rDNA): in the context of the Guidelines, rDNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.
Select Agent: Biological materials that have been restricted by the Department of Health and Human Services (DHHS) and the Animal and Plant Health Inspectional Services (APHIS) because of a perceived risk of bioterrorism through improper possession or use. Laboratories that wish to conduct research on these materials must follow strict guidelines that include registration of the entity, laboratory, and personnel with DHHS/APHIS prior to obtaining agents and starting research.
Risk Group: NIH classification of microbiological agents based on association with and resulting severity of disease
Risk Group 1: Agents that are not associated with disease in healthy adult humans

Risk Group 2: Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available
Risk Group 3: Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available
Rick Group 4; Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available

Any other terms, not specifically defined herein, shall have the meaning as defined in the Guidelines. If the Guidelines do not define the term, it shall have the meaning as is commonly used.

SECTION 4: PERMIT REQUIREMENT

Any institution proposing to process or use Biological Agents or rDNA must obtain a permit from the Arlington Board of Health before engaging in any activity, including construction or renovation of facilities.

SECTION 5: TERMS AND CONDITIONS

1) All rDNA materials and Biological Agents classified as Risk Group 4 agents by the Guidelines, or any work with rDNA materials or a Biological Agent that requires BSL-4 containment based on a biological risk assessment shall be prohibited in the Town of Arlington.
2) Institutions applying for a permit must complete and submit the Plan Review Packet for the use of Biological Agents and/or rDNA within the Town of Arlington. The Director of Health and Human Services or his or her designee will review said application and make its recommendation to the Board of Health. A hearing with the Board of Health will be scheduled within sixty (60) days after the application is filed to take action on the application. The period within which final action shall be taken may be extended for a definite period by mutual consent of the Board of Health and applicant.
3) Each institution must designate an individual as the point of contact for the permit process. This person may be the biosafety officer or responsible official or may serve the institution in another capacity.
4) Institutions must comply with this regulation and the Guidelines at all times.
5) Institutions must allow inspections of both facilities and records, as related to these regulations, in response to emergencies and at other times deemed necessary by the Board of Health.
6) All areas in which rDNA or Biological Agents are utilized shall be free of rodent and insect infestation.

7) Institutions must adhere to a Health and Safety Manual, prepared by the institution, which contains all procedures relevant to the use of Biological Agents and rDNA at all levels of containment at use at the institution. The manual shall also contain a plan for waste disposal in compliance with all applicable federal, state, and local laws or regulations.
8) Institutions must establish and implement a training program of safeguards and procedures for both laboratory personnel using Biological Agents and/or rDNA and non-laboratory personnel who may come into contact with these materials.
9) Each institution shall establish an Institutional Biosafety Committee (IBC) which shall meet at least annually. The IBC shall be established in accordance with the Guidelines defined above, except that the required composition of each IBC shall include at least one representative from the Town of Arlington, approved by the Board of Health. The community member of the IBC shall have no financial interest in the institution or any other institution in competition therewith, and such representative shall be bound to the same provisions as to nondisclosure and nonuse of proprietary information as all other members of the IBC, except to the extent necessary to alleviate any public health hazard.
10) In accordance with the Guidelines, the IBC, acting on behalf of an institution, shall review all rDNA and Biological Agent use for compliance with the Guidelines and approve those projects that conform to the Guidelines. A description of each protocol approved by the IBC, including all organisms and the containment to be used, and a statement certifying that the experiment conforms with the Guidelines shall be filed with the Board of Health.
11) All institutions shall provide an appropriate medical surveillance program as determined by their IBC and consistent with the Guidelines. Each institution shall submit a description of its medical surveillance program and documentation regarding its implementation as part of its annual report.
12) Each institution shall complete an annual report by April 30 of each year. Said reports must include a summary of the work performed over the past year and addressing any ongoing work and in addition the following:
    a. Current list of IBC members
    b. Copies of the previous year's IBC meeting minutes
    c. Summary of research and any changes in the past year
13) All information sent to the Board of Health shall have all proprietary information and trade secrets removed therefrom. The full text shall remain on file in the records of the institution for inspection at all reasonable times by any member of the IBC or The Board of Health or its designee(s). The Board of Health and its designee(s) shall maintain the confidentiality of all proprietary information and trade secrets released to them by reason of these regulations to the extent permitted by law. As used in these regulations, proprietary information and trade secrets shall be defined as set forth in under the laws of the commonwealth of Massachusetts.
14) Every applicant shall submit evidence of, and maintain at all times while conducting activities regulated hereunder, a policy or policies of insurance against liability arising out of activities regulated hereunder, for general liability insurance, and contractual liability insurance covering any indemnification required hereunder or by separate

agreement, each in an amount of at least $1,000,000 for personal injury or death to any one person, and at least $5,000,000 for personal injury or death from any one incident, and at least $1,000,000 for property damage, and in addition, the institution shall have in full force and effect any other particular or special policy of insurance required by law and the Town of Arlington shall be named as an additional insured in all such policies.

15) Each institution engaging in, or intending to engage in, any activities regulated hereunder agrees to indemnify, defend, protect, and hold harmless the Town of Arlington, its selectmen, officers, agents and employees from and against any and all claims, demands, losses, damages, liabilities, fines, charges, penalties, administrative and judicial proceedings and orders, judgments, remedial actions of any kind, all costs and cleanup actions of any kind, and all costs and expenses incurred in connection therewith, including reasonable attorney's fees and costs of defense (collectively, the "losses"), directly or proximately resulting from the institution's negligence with regard to any acts, omissions or conduct in any way related to any activity regulated hereunder, pursuant to its permit, its application therefore, or resulting from the institution's failure to comply with the terms of the permit, the Regulation of the Guidelines.
16) Permits shall be issued and renewed on an annual basis. The fee for issuance and renewal of permits will be set by the Town Manager.

SECTION 6: LARGE SCALE USE

1) Any institution intending to use Biological Agents or rDNA on a large scale requires the expressed written approval of the Arlington Board of Health prior to conducting any such activity.
2) Any currently permitted institution shall request approval to conduct large scale activity from the Board of Health at least thirty (30) days prior to the initiation of any large scale-related activity, which may include, but not be limited to, construction or renovation of facilities. The Board of Health shall act and make a decision on the request within a thirty (30) day period from receipt of the request. Approval request should come in the form of proposed floor plan of the large scale room and IBC application documenting the proposed research and risk assessment by the Biosafety officer/IBC committee. A formal presentation to the Board of Health may be required to review the materials submitted prior to the Board of Health making a final decision to approve the project(s).
3) Institutions which are not currently permitted shall request approval to conduct large scale activity as part of their application for a Biological Agent or rDNA use permit.
4) During the review of the institution's request, the Board of Health may request additional information from the institution pertaining to the proposed large scale activity.

SECTION 7: EMERGENCY RESPONSE

1) The institution shall report immediately, and in no case more than twenty-four (24) hours, to the Board of Health and any other appropriate authorities any significant problems

with or violations of the Guidelines or these regulations, any significant Biological Agent or rDNA- related accidents or illnesses, and any accidental release representing a significant hazard to employees or the public. The initial report shall be provided verbally to the Board of Health, with a written report documenting the initial report to follow within 24 hours. The institution shall provide a final written report to the Board of Health within 30 days of the initial report. The final written report shall include, but not be limited to, information detailing causes, outcomes, response measures, corrective actions and subsequent preventive measures related to the incident.

2) The institution shall provide a plot plan showing the location of all facilities, and a floor plan showing the internal layout of all facilities.
3) The institution shall submit a plan for orienting representatives of the Health, Police and Fire Departments to the facilities and the procedures to be utilized in the event of an emergency.

SECTION 8: ENFORCEMENT

Enforcement of this Regulation shall be the duty and responsibility of the Arlington Board of Health or its designee(s).

SECTION 9: PENALTIES

1) A violation of any condition or restriction of a permit or provision of these regulations shall subject the violator to a fine of three hundred ($300) dollars, or by a criminal complaint in a court of competent jurisdiction. Each day on which any violation exists shall be deemed to be a separate and distinct offense.

2) Once a permit has been issued it may be revoked, suspended, or modified, by the Board of Health, or not renewed upon a determination, after due notice and hearing, that the institution involved has materially failed to comply with these regulations or the permit requirements, and terms and conditions, including adherence to the Guidelines.

3) Notwithstanding the above, the Board of Health, upon determination that any violation constitutes an immediate or severe threat to the public health and safety, may order the necessary remedial actions up to and including the immediate closure of any premises or laboratory engaging in or contributing to such threat, without prior notice and hearing but with subsequent notice and hearing within reasonable time.

SECTION 10: EXCLUSIONS

The provisions of this Regulation are not intended to apply to clinical, non-research operations of doctors, dentists and veterinarians within the Town of Arlington when governed by other local, state and federal agencies and regulations.

SECTION 11: SEVERABILITY
The provisions of this section are severable; and if any of the provisions of these regulations shall be held unconstitutional or otherwise invalid by any court of competent jurisdiction, the decision of such court shall not affect or impair any of the remaining provisions.

Arlington Board of Health

Michael Fitzpatrick, DMD, Chair
Gregory Leonardos
Marie Walsh Condon, MD

APPENDIX 4 RECOMBINANT DNA REGISTRATION FORM

TetraGenetics Inc.
Institutional Biosafety Committee

19 Mystic Street
Arlington, MA

Recombinant DNA (rDNA) Project Registration Form

Protocol Number:

Title:

Principal Investigator:	
Address:	
Phone:	
Fax:	
Email:	
Home Phone:	

The signatures below represent the acceptance of responsibility for completeness of this project registration form, and compliance with all local, state and federal regulations and laws pertaining to the use of rDNA covered under this protocol. Copies of this protocol must be provided to the individuals working under it and to other TetraGenetics staff as requested or required.

Principal Investigator's Signature: _____ Date:_____

Program Director Signature:_____ Date:_____

This protocol has been reviewed and accepted by the TetraGenetics Institutional Biosafety Committee (IBC). Please note that approval is not final until the principal investigator receives written confirmation of the approval.

IBC Chairman:_____ Date:_____

A. Project Classification

Please review the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules and then check the appropriate level for this project registration in the chart below.

Check	Level	Approval/Review	Examples
	III-A	NIH Director, RAC, IBC	A drug resistant gene transferred into a (new) microorganism.
	III-B	NIH/OBA, IBC	The cloning of toxin molecules with LD_{50} < 100 ng/kg of body weight.
	III-C	RAC, IRB, IBC	Recombinant DNA (or DNA or rDNA derived from rDNA) transferred into humans.
	III-D	IBC†	Recombinant DNA transferred to or from whole animals, whole plants, transgenic rodents, experiments involving >10 Liters of culture, or agents listed in Risk Groups 1, 2, 3, or 4 (see below) at the appropriate Biological Safety Level (BL).
	III-E	IBC§	Recombinant DNA involving no more than 2/3 eukaryotic virus agents, whole plants, arthropods, or transgenic rodents.
	III-F	Exempt	Recombinant DNA not found in organisms or viruses, single monochromal or viral DNA sources, or host DNA transferred to the same host or related species.

† Approval required before initiation.

§ Notify IBC when project is initiated. IBC approval still required.

B. Project Goals

Please give a brief summary of project goals stated in non-technical terminology.

C. Technical Description of Experiments

Provide a technical description of experiments. Include enough detail that referencing other documents or scientific papers would not be necessary.

C.1. What is the source of the DNA/RNA?

Include gene names and organism of origin.

C.2. What is the nature of the DNA/RNA segment to be inserted?

Does the insert code for a toxin, what percentage of viral genome is eukaryotic, etc?

C.3. What hosts and/or vectors will be used?

List all prokaryotic and eukaryotic hosts.

C.4. Will non-recombinant microorganisms be used?

Describe other potential sources of microorganisms, such as etiologic agents, blood, tissues, etc.

C.5. What is the scale of work?

Bench scale <9.9 liters, or production scale >9.9 liters

C.6. Will animals be used under this project registration?

Outline procedures animals use is required for. IACUC review will be necessary for any experiments involving animals.

If yes, specify:

Host

Vectors

Inserted DNA

What fraction of eukaryotic viral genome is contained in the recombinant molecule?

C.7. Will plants be used under this project registration?

If yes, specify:

Host

Vectors

Inserted DNA

What fraction of eukaryotic viral genome is contained in the recombinant molecule?

D. Occupational Health and Safety

Please check off the categories below that apply to this protocol. Discuss in detail below what procedures will be followed to assure proper protection of personnel.

D.1. Please state biosafety level work will be conducted at and include a justification for choosing this level.

All work included in this project registration will be conducted according to the policies and procedures outlined in TetraGenetics Inc. biosafety manual and exposure control plan, including but not limited to general handling, equipment use and waste procedures.
PI INITIALS:_____

D.2. Other safety considerations

Check	Safety Considerations
	Radioisotopes (may require changes to MA radiation materials license)
	Chemical Hazards
	Controlled Substances
	Primary Human Tissue (requires BBP training)
	Other

D.3. Use as much space as necessary to fill in fields below.

Specific Hazard	Category	Precautions

E. Personnel

Provide below the names, titles and training each person working under this protocol has received. Include number of years working with rDNA and specific details of experience. Use as much space as is necessary. A copy of each individuals CV must also be on file.

Name	Title

F. Location of rDNA Use

Please list room numbers or names where work will take place.

G. Transfer of Materials

Will any of the materials be shipped between facilities? Please copy chart for each co-investigator.

Name	
Address	
Phone	

APPENDIX 5 RETROVIRAL VECTORS

Retrovirus	Genus	Receptor	Type	Function	Tropism
MoMLV	Gammaretrovirus	CAT-1	TM14	Amino acid transport	Ecotropic, mouse
X-MLV	Gammaretrovirus	XPR1	TM8	Unknown	Xenotropic, human, others
P-MLV	Gammaretrovirus	XPR1	TM8	Unknown	Polytropic. mouse and human
A-MLV	Gammaretrovirus	Pit-2	TM10-13	Phosphate transport	Amphotropic, mouse and human
GALV	Gammaretrovirus	Pit-1	TM10-13	Phosphate transport	Primate and human
HERV-W	Gammaretrovirus	RDR	TM9-10	Amino acid transport	Human
SRV-1-5	Gammaretrovirus	RDR	TM9-10	Amino acid transport	Primate
HIV-1, HIV-2	Lentivirus	CD4, CCR5/CXCR4	TM1, TM7	MHCII binding, Chemokine receptor	Human
SIV-1	Lentivirus	CD4, CCR5, Others	TM1, TM7	MHCII binding, Chemokine receptor	Primate, Human
FIV-1	Lentivirus	CXCR4, HS	TM7	Chemokine receptor	Feline, Human

Abbreviations:
MoMLV is Moloney Murine Leukemia Virus; X-MLV is xenotropic MLV; P-MLV is polytropic MLV; A-MLV is amphotropic MLV; GALV is gibbon ape Leukemia virus; HERV-W is human endogenous retrovirus group W; SRV 1-5 is simian retroviruses 1-5; HIV is human immunodeficiency virus; SIV is simian human immunodeficiency virus; FIV is feline immunodeficiency virus; CAT-1 is cationic amino acid transporter 1; XPR-1 is xenotropic, polytropic receptor 1; PIT ½ is phosphate transporter 1 or 2; RDR is RD-114 and D-type retrovirus receptor; CCR5 is C-C chemokine receptor 5; CXCR4 is CXC chemokine receptor 4; HS is heparin sulfate; TM is transmembrane.

This table was reproduced from *Safety Considerations for Retroviral Vectors: A Short Review*, page 5, prepared by Donald E. Mosier, TSRI Institutional Biosafety Committee Chair with the assistance of Carolyn Keierleber, TSRI Biosafety Officer and Associate Director of Environmental Health & Safety and Richard Gulizia, TSRI BL-3 Facility Director.

APPENDIX 6 SELECT AGENTS LIST

The following biological agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of the Select Agent Regulations. The list of excluded agents and toxins can be found at:
https://www.selectagents.gov/SelectAgentsandToxinsExclusions.html.

HHS AND USDA SELECT AGENTS AND TOXINS
7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS

Abrin
Bacillus cereus Biovar *anthracis**
Botulinum neurotoxins*
Botulinum neurotoxin producing species of *Clostridium**
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)[1]
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus[3]
Ebola virus*
*Francisella tularensis**
Lassa fever virus
Lujo virus
Marburg virus*
Monkeypox virus[3]
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
Ricin
Rickettsia prowazekii
SARS-associated coronavirus (SARS CoV)
Saxitoxin
South American Haemorrhagic Fever viruses:
- Chapare
- Guanarito
- Junin
- Machupo
- Sabia

Staphylococcal enterotoxins A,B,C,D,E subtypes
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses:
- Far Eastern subtype
- Siberian subtype

Kyasanur Forest disease virus
Omsk hemorrhagic fever virus
Variola major virus (Smallpox virus)*
Variola minor virus (Alastrim)*
*Yersinia pestis**

OVERLAP SELECT AGENTS AND TOXINS

*Bacillus anthracis **
Bacillus anthracis Pasteur strain
Brucella abortus
Brucella melitensis
Brucella suis
*Burkholderia mallei**
*Burkholderia pseudomallei**
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus[3]

USDA SELECT AGENTS AND TOXINS

African horse sickness virus
African swine fever virus
Avian influenza virus[3]
Classical swine fever virus
Foot-and-mouth disease virus*
Goat pox virus
Lumpy skin disease virus
Mycoplasma capricolum[3]
Mycoplasma mycoides[3]
Newcastle disease virus[2,3]
Peste des petits ruminants virus
Rinderpest virus*
Sheep pox virus
Swine vesicular disease virus

USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS

Peronosclerospora philippinensis (Peronosclerospora sacchari)
Phoma glycinicola (formerly Pyrenochaeta glycines)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae

*Denotes Tier 1 Agent

[1] C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins α-MI and α-GI (shown above) as well as α-GIA, Ac1.1a, α-CnIA, α-CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

[2] A virulent Newcastle disease virus (avian paramyxovirus serotype 2) has an intracerebral pathogenicity index in day-old chicks (Gallus gallus) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

[3] Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus , west African clade of Monkeypox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies Mycoplasma capricolum except subspecies capripneumoniae (contagious caprine pleuropneumonia), all subspecies Mycoplasma mycoides except subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia), any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, and Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3, provided that the individual or entity can verify that the agent is within the exclusion category.

9/10/13

APPENDIX 7 SCHEDULE OF CLEANING AND DECONTAMINATION

Below is the routine cleaning schedule for equipment used with bloodborne pathogens. As noted in the exposure control plan, all equipment is immediately cleaned after a spill occurs.

EQUIPMENT	**FREQUENCY**	**DISINFECTANT**	**PROCEDURE**
Incubators	Monthly	70% ethanol	Wipe down surfaces, autoclave shelves
BSC	Daily, as used	10% bleach followed by 70% ethanol	Wipe down surfaces. Lift grates and clean under work area as needed.
Biowaste lids	When boxes are closed for disposal	70% ethanol	Wipe all surfaces (top and underneath)
Centrifuges	Monthly	10% bleach followed by 70% ethanol	Wipe down surfaces, including centrifuge buckets and caps.

APPENDIX 8 SHARPS EVALUATION FORM

The federal Needlestick Safety and Prevention Act requires the investigation and use of sharps with engineered injury protections or needleless systems whenever possible. An example of this would be the use of a self-sheathing needle.

Input from researchers using sharps with human materials is required for the selection and use of safer medical devices. Complete the following initial survey form and return to the Biosafety Officer (BSO).

1. I work with human materials, or other potentially infectious materials (OPIM), such as blood, serum, tissue, bodily fluids or human cell lines.
   □ YES □ NO

2. I use sharps, such as needles, razor blades, or scalpels in my work with human materials or OPIM.
   □ YES □ NO

   If you answered no to question #2, skip the rest of the form, sign and return to the BSO.

3. The tasks that involve the use of needles or sharps are (briefly describe):

4. Have you seen devices on the market that may make your work safer or reduce the risk of sharps injury?
   □ YES □ NO

5. If yes, indicate the vendor and part number, as well as the vendor phone number or website link below.

6. Are you interested in participating on an informal committee to select and evaluate sharps with engineered sharps injury protections and needleless systems when more become available to the market?
   □ YES □ NO

NOTE: If you come across a new engineered device that can be used in your work, bring it to the attention of the BSO for evaluation immediately.

Print Name: _____

Signature: _____

Date: _____

Department: _____

APPENDIX 9 RECEIPT AND TRANSPORT OF BIOLOGICAL MATERIALS

General Guidelines for Receipt of Delivered Biological Materials

1. Do not handle the package directly if the packaging looks compromised.
2. If the package is damaged or leaking, put the package in a secondary container and call the Biological Safety Officer.
3. Handle the package as a biological spill.

General Guidelines for Transport of Biological Materials

1. Transport all BL2 and above materials in a labeled, sealable, unbreakable secondary container. This can be a zip-lock bag, tupperware container, or biocarrier.
2. Packages of infectious or potentially infectious agents must be labeled with the universal biohazard symbol.

Regulated Material	Permit Application/Regulating Agency
Recombinant DNA Materials	Compliance with the NIH guidelines for rDNA work. USDA PPQ 1001 if plant, animal or soil material is infective.
Certain Human/Animal pathogens and all foreign human specimens (Receipt of human specimen from some areas is prohibited. Consult with the USDA/CDC as early as possible.)	CDC 0.753 Center for Disease Control Biosafety Office 1600 Clifton Road, N.E. Atlanta, GA 30333 (404) 639-3883 https://www.cdc.gov/phpr/ipp/index.htm
Foreign animal cell cultures, foreign derived products, sera, hormones, milk, etc. Domestic pathogens and all foreign source material from animals, plants and soil.	USDA VS 16-3 MA US Department of Agriculture Animal and Plant Inspection Service 10 Causeway Street Boston, MA 02222 (617) 565-7030 Boston office must approve before they forward request to Riverdale office. Inspectors may visit.

For information, advice and forms:	U.S. Department of Agriculture Animal and Plant Inspection Service 4700 River Road Riverdale, MD 20737 1-844-820-2234

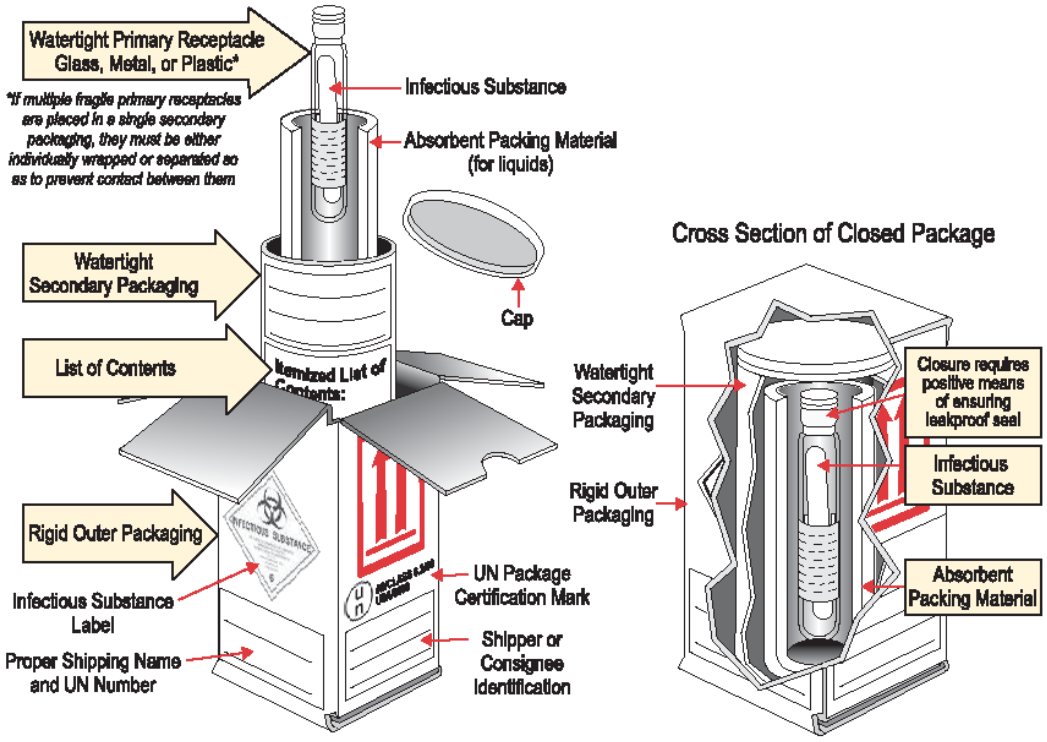
APPENDIX 10 SHIPPING BIOHAZARDOUS SUBSTANCES

Department of Transportation (DOT) and International Air Transport Association (IATA) regulations must be followed for all shipments. Anyone who ships hazardous materials must be trained in DOT and IATA regulations.

Packaging and labeling requirements for interstate shipment of infectious substances (etiologic agents) and clinical specimens.

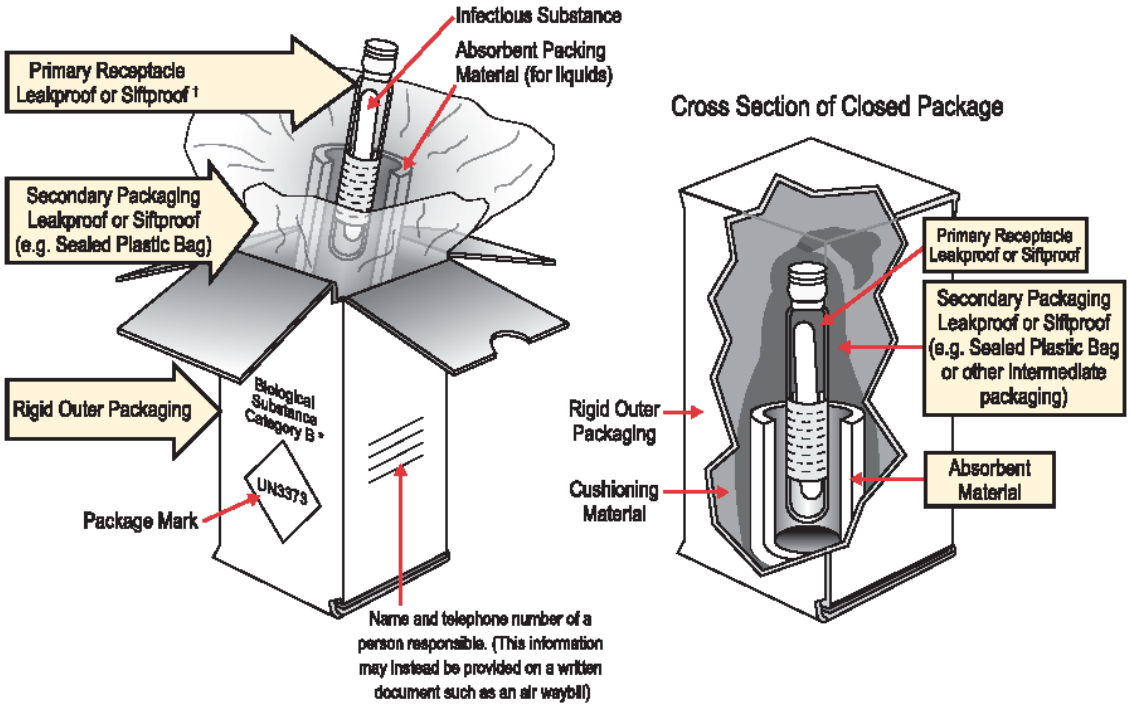
Note that the shipper's name, address and telephone number must be on the outer and inner containers. Refer also to additional provisions of the Department of Transportation (49 CFR Parts 171-180) Hazardous Materials Regulations.

Category A - Infectious Substance



Note 1: *The smallest external dimension of the outer packaging must not be less than 100 mm (3.9 inches)*
Note 2: *The primary receptacle or the secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa*
Note 3: *Follow package manufacturer's closure instructions*

Category B - Biological Substance



* *The proper shipping names "Biological Substance, Category B"; "Clinical Specimen"; and "Diagnostic Specimen" are authorized until December 31, 2006. From January 1, 2007 only the proper shipping name "Biological Substance, Category B" will be authorized.*

† *If multiple fragile primary receptacles are placed in a single secondary packaging they must be either individually wrapped or separated to prevent contact*

Note: *Follow package manufacturer's closure instructions*

APPENDIX 11 AUTOCLAVE SAFETY

Every autoclave is different, so refer to the operator's manual for specific instructions on operation of the autoclave.

Procedure

There are several practices that will minimize the chance of a serious accident occurring, but also increases the functionality of the autoclave.

1. Before using the autoclave, check to make sure no items were left inside by the previous user that could pose a hazard.
2. Clean the drain strainer before loading the autoclave
3. Load the autoclave properly as per manufacturer's recommendations.
4. Before loading containers of liquids into the autoclave, the caps must be loosened to avoid having the bottles shatter during pressurization.
5. Individual glassware pieces should be in heat resistant plastic trays on a shelf or rack and never placed directly on the autoclave bottom or floor.
6. Use a tray with a solid bottom and walls to contain the contents and catch spills.
7. Add ¼ to ½ inch of water to the tray so the bottles will heat evenly.
8. Make sure plastic materials are compatible with being autoclaved.
9. Make sure the autoclave door is fully closed and latched and the correct cycle is selected before starting the cycle.
10. Wear heat resistant gloves when operating the autoclave door after a cycle.
11. If the door must be opened prior to the "cool down" cycle being completed, stand behind door when opening and beware rush of steam. Be sure to wear eye and face protection.
12. For non-liquid glassware loads allow the material to cool for 15 minutes prior to touching it with ungloved hands. If the material is waste wear at least latex or equivalent gloves to place the waste in the proper medical waste container.
13. For liquid loads allow the material to cool for one (1) hour before touching with ungloved hands. Inform others in the area that a heat hazard is present.
14. When removing items from the autoclave, wear heat resistant gloves. A rubber apron is also recommended.

Prohibited autoclave activities

NEVER put solvents, volatile or corrosive chemicals (such as phenol, chloroform, bleach, etc.) or radioactive materials in an autoclave. Call the Safety Officer if you have questions about proper disposal of these materials.

APPENDIX 12 DISINFECTANTS

SUMMARY OF PRACTICAL DISINFECTANTS

	Quaternary ammonium compounds	Phenolic compounds	Chlorine compounds	Iodofors	Ethyl alcohol	Isopropyl alcohol	Form-aldehyde	Glutar-aldehyde
Inactivates								
Vegetative bacteria	+	+	+	+	+	+	+	+
Lipoviruses	+	+	+	+	+	+	+	+
Nonlipid viruses	-	**a**	+	+	**a**	**a**	+	+
Bacterial spores	-	-	+	+	-	-	+	+
Treatment requirements								
Use dilution	**0.1-2.0%**	**1.0-5.0%**	**500ppm[b]**	**25-1600 ppm[b]**	**70-85%**	**70-85%**	**0.2-8.0%**	**2%**
Contact time (min)								
Lipoviruses	**10**	**10**	**10**	**10**	**10**	**10**	**10**	**10**
Broad spectrum	**NE**	**NE**	**30**	**30**	**NE**	**NE**	**30**	**30**
Important characteristics								
Effective shelf life >1 week [c]	+	+	-	+	+	+	+	+
Corrosive	-	+	+	+	-	-	-	-
Flammable	-	-	-	-	+	+	-	-
Explosive potential	-	-	-	-	-	-	-	-
Inactivated by organic matter	+	-	+	+	-	-	-	-
Skin irritant	+	+	+	+	-	-	+	+
Eye irritant	+	+	+	+	+	+	+	+
Respiratory irritant	-	-	+	-	-	-	-	-
Toxic [d]	+	+	+	+	+	+	+	+
Applicability								
Waste liquids	-	-	+	-	-	-	-	-
Dirty glassware	+	+	+	+	+	+	+	+
Equipment, surface decon.	+	+	+	+	+	+	+	+
Proprietary products [e]	CDQ	Hil-Phene	Chloramine T	Hy-Sine			Sterac	Cidex
	End-Bac	**Matar**	**Clorox**	**Ioprep**				
	Hi-Tor	**Mikro-Bac**	**Purex**	**Mikroklene**				
	Mikro-Quat	**O-Syl**		**Wescodyne**				

+ = Yes; - = No; NE = Not effective
[a] Variable results depending on virus
[b] Available halogen
[c] Protected from light and air
[d] By skin or mouth or both. Refer to manufacturer's literature or Merck Index.
[e] Space limitations preclude listing all products available. Individual listings (oromissions) do not imply endorsement (or rejection) of any product by the National Institutes of Health or the U. S. Environmental Protection Agency.

Source: Van Houten, J., 1989. New Frontiers in Biosafety: The Industrial Perspective. *In* Biohazard Management Handbook, Liberman, D.F. & Gordon, J.G. (Eds), pp.199-200, New York, Marcel Dekker, Inc.

ACTIVITY LEVELS OF SELECTED DISINFECTANTS		
Class	**Use-Concentration of Active Ingredient**	**Activity Level**
GAS		
Ethylene oxide	450-500 mg/L*	High
LIQUID		
Glutaraldehyde, aqueous **	2%	High
Formaldehyde + alcohol	8% + 70%	High
Stabilized hydrogen peroxide	6-10%	High
Formaldehyde, aqueous	3-8%	High to intermediate
Iodofors	30-50 mg/L free iodine / 20-150 mg/L available iodine***	Intermediate
Iodine + alcohol	0.5% + 70%	Intermediate
Chlorine compounds	0.1 - 0.5% free chlorine	Intermediate
Phenolic compounds, aqueous	0.5 - 3%	Intermediate to low
Quaternary ammonium compounds	0.1 - 0.2% aqueous	Low
Mercurial compounds	0.1 - 0.2%	Low

* In autoclave-type equipment at 55° to 60° C.

** There are several proprietary formulations on the U.S. market, i.e., 4% glutaraldehyde and 3% formaldehyde; glutaraldehyde 2% and 7% buffered phenol; and glutaraldehyde 2%, low pH and normal and raised temperatures.

*** There are semantic problems associated with iodofors, available iodine, and free iodine.

PREPARATION AND STABILITY OF CHLORINE SOLUTIONS

	Desired chlorine concentration			
	5000 ppm	**1000 ppm**	**500 ppm**	**100 ppm**
Dilution of bleach (5.25% NaOCl) prepared fresh for use within 24 hr	1:10*	1:50	1:100	1:500
Dilution of bleach (5.25% NaOCl) prepared fresh and used for 1-3 days	1:5†	1:25	1:50	1:250

* To achieve a 1:10 dilution, add one part bleach to nine parts water.
† To achieve a 1:5 dilution, add one part bleach to four parts water.

Reference: Rutala, W.A., APIC Guidelines for selection and use of disinfectants, Am J Infect Control, 24:326,1996.

INACTIVATION OF HBV AND HIV BY DISINFECTANTS

Disinfectant	**Concentration inactivating 10^8 HBV in ST, 10 min, 20° C***	**Concentration inactivating 10^5 HIV in ST, ≤ 10 min, 25° C †**
Ethyl alcohol	ND	50%
Glutaraldehyde	2%	ND‡
Glutaraldehyde-phenate	0.13% glutaraldehyde-0.44% phenate	ND
Hydrogen peroxide	ND	0.3%
Iodophor	80 ppm	ND
Isopropyl alcohol	70%	35%
Paraformaldehyde	ND	0.5%
Phenolic	ND	0.5%
Sodium hypochlorite	500 ppm	50 ppm

ST - Suspension test; ND - No data
* Data from Bond *et al*.[92]
† Data from Martin *et al*.[95] Also see Sattar and Springthorpe [96] for data concerning activity of other disinfectants HIV.

From: APIC Guidelines for Selection and Use of Disinfectants, Rutala, W.A., Am J Infect Control. 24:322,1996.

APPENDIX 13 BLOODBORNE PATHOGENS TRAINING OUTLINE

A. Occupational Safety and Health Administration (OSHA): Bloodborne Pathogen Standard

1. Purpose: To minimize or eliminate occupational exposure to blood or other potentially infectious materials (human blood and body fluids, tissues, cell lines, etc.) since an exposure could result in transmission of bloodborne pathogens which could lead to disease or death.

2. Scope: Covers all employees who could be "reasonably anticipated" as a result of performing their job duties to have contact with blood and other potentially infectious materials.

B. Training Requirements

1. Employees receive training upon employment or assignment to tasks involving the potential for occupational exposure.

2. Annual retraining is required.

C. Bloodborne Pathogens and Occupational Transmission

1. Definition: Bloodborne pathogens are microorganisms (virus, bacteria, etc.) found in human materials that may cause disease in humans.

2. Current epidemiology, exposure and symptoms data are discussed for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV).

3. Occupational routes of transmission:
   a. Needlestick or cut/puncture with sharp object
   b. Splash or splatter to face or exposed skin
   c. Contact with non-intact skin (i.e. chapped skin)

4. Other transmission routes

D. Exposure Control Plan
1. Review of job titles and specific job tasks where there is reasonably anticipated exposure.

2. Review of Universal Precautions and Standard Operating Procedures (SOP's):
    a. engineering and work practice controls
    b. safer sharps initiatives
    c. personal protective equipment
    d. housekeeping (cleaning/decontamination schedule)
    e. labels and signs

E. Hepatitis B Vaccine

1. Safe and effective vaccine available for immunization against HBV.

2. A series of 3 vaccinations.

3. Vaccination against HBV is made available free of charge to all employees who have occupational exposure to blood and other potentially infectious materials.

4. Employees must sign a declination form if they choose not to be vaccinated, but may later request and receive the vaccine at no cost.

F. Exposure Management

1. Review of exposure incidents (needlesticks, etc.)

2. Procedure to follow in the event of an exposure:
    a. wash the exposed area with soap and water
    b. notify your supervisor immediately
    c. go to the designated occupational medicine provider

3. Medical assessment, treatment, follow-up and counseling:
    a. confidential
    b. no cost to the employee

4. Limitations of protection devices

G. Recordkeeping Requirements

1. Training Records

2. Medical Records

APPENDIX 14 SHARPS INJURY LOG

If an OSHA recordable sharps injury occurs, this form must be completed in addition to the OSHA 300 form. Complete the form below for all occupational exposures to blood or OPIM that occur from a sharps injury.

OSHA Log Reference #	Device Involved in Incident	Brand of Device Involved in Incident	Location of Incident	Description of Incident

APPENDIX 15 HEPATITIS B VACCINATION FORM

The OSHA Bloodborne Pathogens Standard, 29 CFR 1910.1030, requires that the hepatitis B vaccination be made available to all employees who are occupationally exposed to human source materials including blood, serum, plasma and all other potentially infectious materials (OPIM). The vaccine is offered after the employee has received bloodborne pathogens (BBP) training as required by the standard and within 10 working days of initial assignment. Vaccination is encouraged unless, 1) the employee has already had the hepatitis B vaccination series; 2) antibody testing has revealed that the employee is immune; or 3) the vaccine is contraindicated for medical reasons. The employee is given the option to accept or decline the vaccination after being told of the benefits and risks of the vaccine during BBP training.

The availability of the Hepatitis B vaccine is part of the company's compliance to the BBP standard, which also includes:

1. An exposure control plan
2. New employee and annual training
3. A safer sharps program
4. A sharps injury log

The attached hepatitis B vaccine form must be completed by all employees during bloodborne pathogens training. If the hepatitis vaccine is declined initially, the employee can choose to receive it at any time during employment at no cost to them, including post-exposure, change of assignment or at any other time.

CHECK AND SIGN **ONE** OF THE FOLLOWING BOXES:

DECLINATION

□ I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring a hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with the hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with the hepatitis B vaccine, I can receive the vaccination series at no charge to me.

_____	_____	_____
PRINT NAME	**SIGNATURE**	**DATE**

CONSENT FOR VACCINE AND TITER

□ I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring a hepatitis B virus (HBV) infection. I understand the risks and benefits of the hepatitis B vaccine and that I will need to receive a series of three shots followed by a scheduled titer to complete the vaccine. I would like to participate in the hepatitis B vaccination program as offered by the Tetragenetics. The vaccination series and titer are offered at no cost to me. I agree to go to Mount Auburn Occupational Health Center, located at 725 Concord Ave., Cambridge to participate in this program.

_____	_____	_____
PRINT NAME	**SIGNATURE**	**DATE**

Shot 1: _____	**Shot 2: _____**	**Shot 3: _____**	**Titer: _____**
DATE	**DATE**	**DATE**	**DATE**

STATEMENT OF PREVIOUS IMMUNIZATION

□ I attest that I have previously been immunized against hepatitis B virus (HBV) infection. Please list the dates (month/year) of the three shots.

Shot 1: _____	**Shot 2: _____**	**Shot 3: _____**	**Titer: _____**
DATE	**DATE**	**DATE**	**DATE**

□ I have previously received the hepatitis B vaccination, but I would like to have my titer evaluated and a booster administered if necessary.

Titer: _____	**Booster (if necessary): _____**
DATE	**DATE**

_____	_____	_____
PRINT NAME	**SIGNATURE**	**DATE**

APPENDIX 16 INCIDENT REPORT

Date of Injury:_____

Employee Name: _____ Employee Signature: _____

Describe the incident in a detailed manner. Explain what the injury was, where it occurred, how it happened and, if a sharp was involved, what type of sharp it was. Include the manufacturer of the sharp, if possible.

Was the employee exposed directly to human source materials or OPIM? YES NO

If yes, is serological, PCR or similar data available for the material? YES NO

Was the employee referred to Occupational Health for counseling on the exposure? YES NO
If yes, attached physician's written opinion to this form.

Did Occupational Health review the data for the source material, if it was available? YES NO

Does the employee require follow-up medical evaluation at Occupational Health? YES NO
If yes, attached physician's written opinion to this form.

Describe any corrective actions and/or preventative measures to be taken to avoid this type of accident in the future.

Safety Officer Signature: _____ Date: _____

Safety Partners, Inc.
19A Crosby Drive
Bedford, MA 01730
781-222-1022
info@safetypartnersinc.com
www.safetypartnersinc.com

Town of Arlington
Department of Health and Human Services
Office of the Board of Health
27 Maple Street
Arlington, MA 02476
Tel: (781) 316-3170
Fax: (781) 316-3175

Biosafety and Recombinant DNA Regulations

SECTION 1: AUTHORITY

On April 11, 2012 the Arlington Board of Health, pursuant to the authority granted under Massachusetts General Laws (M.G.L.), Chapter 111, Section 31, voted to adopt the "**Biosafety and Recombinant DNA Regulations**" to protect the public health of the community.

SECTION 2: APPLICABILITY/ PURPOSE

These regulations shall apply to all research, production, and other associated activities involving rDNA materials or Biological Agents undertaken within the Town of Arlington, Massachusetts. All such activities shall be undertaken only in strict conformity with these regulations and with current National Institutes of Health (NIH) Guidelines (hereinafter referred to as the "Guidelines") as defined below herein § 3. Any institution engaged in research or production involving rDNA materials or Biological Agents shall also comply at all times with any other applicable federal and state regulations covering such work, including regulations promulgated by the Centers for Disease Control (CDC), Occupational Safety Health Administration (OSHA), Environmental Protection Agency (EPA) Massachusetts Department of Environmental Protection (MADEP) and Massachusetts Department of Public Health (MADPH).

These regulations are promulgated to ensure proper safe guards are in place for work with Biological Agents and recombinant DNA (rDNA) within the Town of Arlington. These regulations promote the safe and responsible conduct of science by institutions utilizing Biological Agents and rDNA materials, and promote competency and adequate training of laboratory staff in laboratory safety.

SECTION 3: DEFINITIONS

Biological agent: any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, or anything capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment. [from the CDC Select Agents and Toxins Final Rule. 42 CFR § 73.1 Definitions]

BMBL: Biosafety in Microbiological and Biomedical Laboratories. The key recommendations for working with biological materials in the United States (US) published jointly by the CDC and the NIH.

BSL: Biological safety level. There are four biosafety levels which consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facility containment. Each combination is specifically appropriate for the operations performed the documented or suspected routes of transmission of the infectious agents, and the laboratory function or activity.

Biosafety Level One Laboratory (BSL-1): All facilities that meet or exceed the criteria for Biosafety Level 1 containment, according to descriptions in the BMBL; appropriate for agents that are not known to cause disease in normal, healthy humans.

Biosafety Level Two Laboratory (BSL-2): All facilities that meet or exceed the criteria for Biosafety Level 2 containment, according to descriptions in the BMBL; appropriate for handling moderate-risk agents that cause human disease of varying severity by ingestion or through percutaneous or mucous membrane exposure.

Biosafety Level Three Laboratory (BSL-3): All facilities that meet or exceed the criteria for Biosafety Level 3 containment, according to descriptions in the BMBL; appropriate for agents with a known potential for aerosol transmission, for agents that may cause serious and potentially lethal infections and that are indigenous or exotic in origin

Biosafety Level Four Laboratory (BSL-4): All facilities that meet or exceed the criteria for Biosafety Level 4 containment, according to descriptions in the BMBL; appropriate for exotic agents that pose a high individual risk of life-threatening disease by infectious aerosols and for which no treatment is available

CDC: Centers for Disease Control and Prevention

EPA: Environmental Protection Agency

Guidelines: The most recent version of the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant DNA Molecules published in the Federal Register, and any further amendments, wherever published, which are adopted by NIH, or any successor agency thereto.

In the event that the NIH shall abolish or discontinue its Guidelines, those Guidelines in effect at the time of such discontinuance shall remain in effect within the Town of Arlington until further written notice from the Board of Health.

Institution: Any single individual, group of individuals, or organization, whether public or private.

Institutional Biosafety Committee: (IBC) a committee established by an institution in accordance with the Guidelines and the terms set forth in these regulations

Large-scale: The use of more than ten liters of rDNA and/or Biological Agent culture. This threshold shall be based on the cumulative volume of culture in all vessels throughout the institution's facility, not just a single vessel or experiment.

MADEP: Massachusetts Department of Environmental Protection

MADPH: Massachusetts Department of Public Health

OSHA: Occupational Safety and Health Administration

Recombinant DNA molecules (rDNA): in the context of the Guidelines, rDNA molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.

Select Agent: Biological materials that have been restricted by the Department of Health and Human Services (DHHS) and the Animal and Plant Health Inspectional Services (APHIS) because of a perceived risk of bioterrorism through improper possession or use. Laboratories that wish to conduct research on these materials must follow strict guidelines that include registration of the entity, laboratory, and personnel with DHHS/APHIS prior to obtaining agents and starting research.

Risk Group: NIH classification of microbiological agents based on association with and resulting severity of disease

Risk Group 1: Agents that are not associated with disease in healthy adult humans

Risk Group 2: Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available

Risk Group 3: Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available

Rick Group 4; Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available

Any other terms, not specifically defined herein, shall have the meaning as defined in the Guidelines. If the Guidelines do not define the term, it shall have the meaning as is commonly used.

SECTION 4: PERMIT REQUIREMENT

Any institution proposing to process or use Biological Agents or rDNA must obtain a permit from the Arlington Board of Health before engaging in any activity, including construction or renovation of facilities.

SECTION 5: TERMS AND CONDITIONS

1) All rDNA materials and Biological Agents classified as Risk Group 4 agents by the Guidelines, or any work with rDNA materials or a Biological Agent that requires BSL-4 containment based on a biological risk assessment shall be prohibited in the Town of Arlington.
2) Institutions applying for a permit must complete and submit the Plan Review Packet for the use of Biological Agents and/or rDNA within the Town of Arlington. The Director of Health and Human Services or his or her designee will review said application and make its recommendation to the Board of Health. A hearing with the Board of Health will be scheduled within sixty (60) days after the application is filed to take action on the application. The period within which final action shall be taken may be extended for a definite period by mutual consent of the Board of Health and applicant.
3) Each institution must designate an individual as the point of contact for the permit process. This person may be the biosafety officer or responsible official or may serve the institution in another capacity.
4) Institutions must comply with this regulation and the Guidelines at all times.
5) Institutions must allow inspections of both facilities and records, as related to these regulations, in response to emergencies and at other times deemed necessary by the Board of Health.
6) All areas in which rDNA or Biological Agents are utilized shall be free of rodent and insect infestation.
7) Institutions must adhere to a Health and Safety Manual, prepared by the institution, which contains all procedures relevant to the use of Biological Agents and rDNA at all levels of containment at use at the institution. The manual shall also contain a plan for waste disposal in compliance with all applicable federal, state, and local laws or regulations.
8) Institutions must establish and implement a training program of safeguards and procedures for both laboratory personnel using Biological Agents and/or rDNA and non-laboratory personnel who may come into contact with these materials.
9) Each institution shall establish an Institutional Biosafety Committee (IBC) which shall meet at least annually. The IBC shall be established in accordance with the Guidelines defined above, except that the required composition of each IBC shall include at least one representative from the Town of Arlington, approved by the Board of Health. The community member of the IBC shall have no financial interest in the institution or any other institution in competition therewith, and such representative shall be bound to the same provisions as to nondisclosure and nonuse of proprietary information as all other members of the IBC, except to the extent necessary to alleviate any public health hazard.
10) In accordance with the Guidelines, the IBC, acting on behalf of an institution, shall review all rDNA and Biological Agent use for compliance with the Guidelines and

approve those projects that conform to the Guidelines. A description of each protocol approved by the IBC, including all organisms and the containment to be used, and a statement certifying that the experiment conforms with the Guidelines shall be filed with the Board of Health.

11) All institutions shall provide an appropriate medical surveillance program as determined by their IBC and consistent with the Guidelines. Each institution shall submit a description of its medical surveillance program and documentation regarding its implementation as part of its annual report.
12) Each institution shall complete an annual report by April 30 of each year. Said reports must include a summary of the work performed over the past year and addressing any ongoing work and in addition the following:
    a. Current list of IBC members
    b. Copies of the previous year's IBC meeting minutes
    c. Summary of research and any changes in the past year
13) All information sent to the Board of Health shall have all proprietary information and trade secrets removed therefrom. The full text shall remain on file in the records of the institution for inspection at all reasonable times by any member of the IBC or The Board of Health or its designee(s). The Board of Health and its designee(s) shall maintain the confidentiality of all proprietary information and trade secrets released to them by reason of these regulations to the extent permitted by law. As used in these regulations, proprietary information and trade secrets shall be defined as set forth in under the laws of the commonwealth of Massachusetts.
14) Every applicant shall submit evidence of, and maintain at all times while conducting activities regulated hereunder, a policy or policies of insurance against liability arising out of activities regulated hereunder, for general liability insurance, and contractual liability insurance covering any indemnification required hereunder or by separate agreement, each in an amount of at least $1,000,000 for personal injury or death to any one person, and at least $5,000,000 for personal injury or death from any one incident, and at least $1,000,000 for property damage, and in addition, the institution shall have in full force and effect any other particular or special policy of insurance required by law and the Town of Arlington shall be named as an additional insured in all such policies.
15) Each institution engaging in, or intending to engage in, any activities regulated hereunder agrees to indemnify, defend, protect, and hold harmless the Town of Arlington, its selectmen, officers, agents and employees from and against any and all claims, demands, losses, damages, liabilities, fines, charges, penalties, administrative and judicial proceedings and orders, judgments, remedial actions of any kind, all costs and cleanup actions of any kind, and all costs and expenses incurred in connection therewith, including reasonable attorney's fees and costs of defense (collectively, the "losses"), directly or proximately resulting from the institution's negligence with regard to any acts, omissions or conduct in any way related to any activity regulated hereunder, pursuant to its permit, its application therefore, or resulting from the institution's failure to comply with the terms of the permit, the Regulation of the Guidelines.
16) Permits shall be issued and renewed on an annual basis. The fee for issuance and renewal of permits will be set by the Town Manager.

SECTION 6: LARGE SCALE USE

1) Any institution intending to use Biological Agents or rDNA on a large scale requires the expressed written approval of the Arlington Board of Health prior to conducting any such activity.
2) Any currently permitted institution shall request approval to conduct large scale activity from the Board of Health at least thirty (30) days prior to the initiation of any large scale-related activity, which may include, but not be limited to, construction or renovation of facilities. The Board of Health shall act and make a decision on the request within a thirty (30) day period from receipt of the request. Approval request should come in the form of proposed floor plan of the large scale room and IBC application documenting the proposed research and risk assessment by the Biosafety officer/IBC committee. A formal presentation to the Board of Health may be required to review the materials submitted prior to the Board of Health making a final decision to approve the project(s).
3) Institutions which are not currently permitted shall request approval to conduct large scale activity as part of their application for a Biological Agent or rDNA use permit.
4) During the review of the institution's request, the Board of Health may request additional information from the institution pertaining to the proposed large scale activity.

SECTION 7: EMERGENCY RESPONSE

1) The institution shall report immediately, and in no case more than twenty-four (24) hours, to the Board of Health and any other appropriate authorities any significant problems with or violations of the Guidelines or these regulations, any significant Biological Agent or rDNA- related accidents or illnesses, and any accidental release representing a significant hazard to employees or the public. The initial report shall be provided verbally to the Board of Health, with a written report documenting the initial report to follow within 24 hours. The institution shall provide a final written report to the Board of Health within 30 days of the initial report. The final written report shall include, but not be limited to, information detailing causes, outcomes, response measures, corrective actions and subsequent preventive measures related to the incident.
2) The institution shall provide a plot plan showing the location of all facilities, and a floor plan showing the internal layout of all facilities.
3) The institution shall submit a plan for orienting representatives of the Health, Police and Fire Departments to the facilities and the procedures to be utilized in the event of an emergency.

SECTION 8: ENFORCEMENT

Enforcement of this Regulation shall be the duty and responsibility of the Arlington Board of Health or its designee(s).

SECTION 9: PENALTIES

1) A violation of any condition or restriction of a permit or provision of these regulations shall subject the violator to a fine of three hundred ($300) dollars, or by a criminal complaint in a court of competent jurisdiction. Each day on which any violation exists shall be deemed to be a separate and distinct offense.

2) Once a permit has been issued it may be revoked, suspended, or modified, by the Board of Health, or not renewed upon a determination, after due notice and hearing, that the institution involved has materially failed to comply with these regulations or the permit requirements, and terms and conditions, including adherence to the Guidelines.

3) Notwithstanding the above, the Board of Health, upon determination that any violation constitutes an immediate or severe threat to the public health and safety, may order the necessary remedial actions up to and including the immediate closure of any premises or laboratory engaging in or contributing to such threat, without prior notice and hearing but with subsequent notice and hearing within reasonable time.

SECTION 10: EXCLUSIONS

The provisions of this Regulation are not intended to apply to clinical, non-research operations of doctors, dentists and veterinarians within the Town of Arlington when governed by other local, state and federal agencies and regulations.

SECTION 11: SEVERABILITY

The provisions of this section are severable; and if any of the provisions of these regulations shall be held unconstitutional or otherwise invalid by any court of competent jurisdiction, the decision of such court shall not affect or impair any of the remaining provisions.

Arlington Board of Health

Michael Fitzpatrick, DMD, Chair
Gregory Leonardos
Marie Walsh Condon, MD

Town of Arlington
Department of Health and Human Services
Office of the Board of Health
27 Maple Street
Arlington, MA 02476
Tel: (781) 316-3170
Fax: (781) 316-3175

MEMO

To: Board of Health Members

From: Kylee Sullivan, Health Compliance Officer

Date: April 5, 2018

RE: Request for Body Art Apprentice Variance

After the last Board meeting on January 31, 2018, it was determined that Ink Jam Tattoo Studio would apply for a variance for a Body Art Apprentice permit as the current *Town of Arlington Rules and Regulations for Body Art Establishments and Practitioners* do not permit Body Art Apprentices. The following is a variance request from Ink Jam owner James Quinn to permit Ms. Ismini Vocas as a Body Art Apprentice. The variance request contains documents that have been adapted from local municipalities (predominantly Cambridge, Medford, and Lowell) that permit Body Art Apprentices through their local regulations. Examples of task sheets, time logs, and skill levels intended to track Apprentice experience and progress are included for your reference.

Currently, Ms. Vocas has provided proof of all practitioner training and experience required in the Town's Body Art Regulations, with the exception of:

> (4) The applicant for a tattoo practitioner permit shall provide documentation, acceptable to the Board, that s/he completed a course on anatomy and physiology with a grade of C or better at a college accredited by the New England Association of Schools and Colleges, or comparable accrediting entity. This course must include instruction on the integumentary system (skin).
>
> (5) The applicant for all practitioners shall submit evidence satisfactory to the Board of at least two years actual experience in the practice of performing body art activities of the kind for which the applicant seeks a body art practitioner permit to perform, whether such experience was obtained within or outside of the Commonwealth.

With regard to requirement (4), Ms. Vocas has a valid Cosmetology License from the State and received training at the Learning Institute for Beauty Science (LIBS) in Malden. Ms. Vocas has had trouble obtaining a copy of her transcript from LIBS due to the school being bought by another institution. According to *240 CMR 4.00: Operation of Cosmetology Schools*, cosmetology curriculum topic requirements include: sanitation, sterilization, hygiene, bones, muscles, nerves, the vascular system, circulation, skin, and personal hygiene. Ms. Vocas hopes her certificate of completion from LIBS will show good faith effort that her training meets the requirements for (4). This variance would enable Ms. Vocas to gain the two years of body art experience required by (5).

I recommend granting Ink Jam a variance for Ms. Vocas to work as a Body Art Apprentice under the condition that she successfully completes Quincy Health Department's Skin Course for Body Artists, or a comparable course, before the end of the 2018 calendar year.

Enclosed please find: the variance documents and applicable components of the *Town of Arlington Rules and Regulations for Body Art Establishments and Practitioners* and *240 CMR 4.00: Operation of Cosmetology Schools.*

March 28, 2018

Town of Arlington
Department of Health and Human Services
Office of the Board of Health
27 Maple Street
Arlington, Ma 02476

RE: Body Art Apprentice Variance for Ismini Vocas

To: Office of the Board of Health, Office of the Public Heath

I want to say thank you to the Town of Arlington, Department of the Board of Health and the Public health for accepting my request and creating an Art Apprentice Variance Program.

I have been looking for a Tattoo Artist, or an Artist that wants to become a Tattoo Artist for quite some time and I have been interviewing many Tattoo Artists for months and no one artist fit the description until I interviewed Ismini Vocas. She is unique, very passionate in the world of art, an amazing artist, business and management oriented, strong customer relations and more. She is highly qualified and fit the description for my shop. Words cannot explain how grateful I am to have the opportunity to pass my craft and skills to Ms Vocas.

I agree to adhere to all regulations, rules, and guidelines regarding body art, body tattooing, and the Art Apprentice Variance from the Arlington Board of Health. I intend to train Ms Vocas in a clean and safe environment following all rules and regulations. I further understand that violation of the regulations, rules, and variance may cause for administrative action by the Board of Health.

Sincerely,

James Quinn
InkJam Tattoo Studio
12 Park Ave
Arlington, MA 02474
Inkjam12@gmail.com

Ismini Vocas
[redacted]

March 28, 2018

Town of Arlington
Department of Health and Human Services
Office of the Board of Health
27 Maple Street
Arlington, Ma 02476

RE: Letter of Intent

To: Head of Office of the Board of Health

I would like to take this opportunity to introduce myself. My name is Ismini Vocas and I have been a resident of Arlington for eight years. I hold a Bachelor's in Science for Management, an Associate's in Science for Business, a Massachusetts license in Hairdressing and Cosmetology, and a Massachusetts license as Life Insurance Agent but art is a significant passion that I have since early childhood. I have taken many different college courses in art, for instance: drawing, photography, installation art, video, sculpting, and other non-college training programs like fashion and design.

Currently I am voluntarily working at Ink Jam Tattoo Studio to learn the business in tattooing and, respecting the Town of Arlington, Board of Health's rules and regulations, one day learn the art of tattooing. I am, honored and humbled to have James Quinn grant me this incredible opportunity to pass his skills on to me based on the merit of my artistic skills, qualifications, and positive attitude towards the future of tattooing. With this opportunity comes respect and responsibility to the Town of Arlington, my clients, Ink Jam Tattoo Studio, and to myself to maintain a clean and safe environment to practice.

Working with James Quinn and the Town of Arlington, Department of The Board of Health, I agree to adhere to all rules and regulations regarding body art and body tattooing. I agree to and adhere to all guidelines and steps in the Body Art Apprentice Variance program. I intend to establish and maintain a safe and healthy working relationship and environment in a professional manner in order to become a professional licensed tattoo artist. I understand that violation of the guidelines, rules and regulations may be cause for administrative action by the Board of Health.

Sincerely,

Ismini Vocas

Introduction

This folder, one out of two, was designed and created by Ink Jam Tattoo Studio, James Quinn and Ismini Vocas. The guidelines used to create and design this folder came from the "Body Art Apprentice Variance" from the Town of Arlington, Department of Health and Human Services.

The, "Body Art Apprentice Variance", is a guideline for Ink Jam Tattoo Studio, Ismini Vocas tattoo apprenticeship. The apprenticeship variance is for two years and needs to renew on a yearly basis therefore we created two identical folders.

The Body Art Variance consists of important documents to include provided by the board of health.

Important documents include:

- Body Art Practitioner Requires valid identification to confirm applicant is at least 18 years of age, address, phone no. email, and emergency contact information.
- Bloodborne, First Aid, and CPR certificates
- Anatomy and Physiology certificate
- Hepatitis B Vaccination status
- Body Art Task sheets and skill level descriptions, (examples taken from the Town of Cambridge and Medford), for the apprentice to master within the two years of apprenticeship and all sheets signed and initialed by the apprentice and assigned supervisor.
- Body Art Time sheet, (example taken from the Town of Lowell), to keep tract of the apprentice hours of work and training, and all forms signed and initialed by the apprentice and assigned supervisor.
- Consent to Tattoo by an Apprentice form filled out and signed by the client. Clients valid ID copied on the back of each form with a picture of the tattoo, dated, comment by the assigned supervisor, a skill level description of the tattoo, and all forms signed and initialed by the apprentice and assigned supervisor.

After the first year of apprenticeship all documents included in this folder copied and kept for Ink Jam Tattoo Studio and the apprentice. The first year completed folder handed to the Town of Arlington, Department of Health and Human Services for the apprentice renewal for the second year.

Table of Contents

TAB 1: **Personal Contact Information and Documents**

Include: (copies)

1. Personal contact information/Emergency form
2. Copy of Drivers License
3. Hepatitis B Vaccination Status
4. Blood borne Pathogen Certificate
5. First Aid/CPR/AED Certificate
6. Anatomy and Physiology
    a. A comparable accredited entity

TAB 2: **Apprentice Time Sheets**

Include: (copies)

1. A time sheet for each month
    a. Day, Comments (training activity conducted), Hours worked, Apprentice Initials, Supervisor Initials, and Total Hours Worked for the Month.

TAB 3: **Tattoo Apprentice Task Sheets**

Include: (copies)

1. Establishment Information
2. Apprentice Information
3. Direction for the Apprentice and Supervisor/Professional Tattoo Artist how to complete Task Sheets
4. Tasks to be mastered by the apprentice
    a. Apprentice demonstrates 13 topics
        - When the apprentice masters each topic the supervisor comments, dates, and initials each topic as complete.
    b. 75 Hours of Direct Observation **(D/O)**
        - When the apprentice completes the hours recommended the supervisor comments, dates, and initials as complete.
    c. 75 Hours of Workstation Clean-Up and Workstation Preparation **(WCU/WP)**
        - When the apprentice completes the hour recommended the supervisor comments, dates, and initials as complete.
    d. Instructions and requirement for level 1,2 and 3 **(L1,L2,L3)**
        - When the apprentice completes each level the supervisor comments, dates, and initials each as complete.

TAB 4: **Consent to Tattoo by Apprentice Level 1**

TAB 5: **Consent to Tattoo by Apprentice Level 2**

TAB 6: **Consent to Tattoo by Apprentice Level 3**

Include: (copies)

a. Ten "Consent to Tattoo by an Apprentice" forms from each level filled out, signed by the client, and initialed by the supervisor and apprentice.
b. On the back of each form will include:
    - The level, date, photo of the tattoo, copy of the clients I.D., and supervisor comments

TAB 7: **Body Art Disclosure Statement**

Tattoo Aftercare Instructions

Name _____

PERSONAL CONTACT INFORMATION

Home Address _____

City, State, Zip _____

Home Telephone# _____ Cell # _____

EMERGANCY CONTACT INFORMATION

1. Name _____ Relationship _____

Address _____

City, State, Zip _____

Home Phone # _____ Cell# _____

Work Phone # _____ Employer _____

2. Name _____ Relationship _____

Address _____

City, State, Zip _____

Home Phone # _____ Cell# _____

Work Phone # _____ Employer _____

MEDICAL CONTACT INFORMATION

Doctor Name _____ Telephone # _____

Dentist Name _____ Telephone # _____

Employee Signiture _____ Date _____

APRIL 2018

Day	Comments	# of Hrs	Apprentice Initial	Supervisor Initials
1	D/O	(12-8) 8HR	IV	JQ
2	WCU/WP, D/O,	(12-8) 8HR	IV	JQ
3	WCU/WP, L1 3HRS,	(12-8) 8HR	IV	JQ
4	L1 3HRS, L2 4 HRS, WCU/WP	(12-8) 8HR	IV	JQ
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				
Total Hours for this Month		32 HRS	6HRS L1, 4HRS L2	

Tattoo Apprentice Task Sheet

Establishment Information:

Name of Establishment: _____

Name of Supervisor / Professional Tattoo Artist _____

Address of Establishment: _____

_____

Apprentice Information:

Apprentice Name: _____

Apprentice Address: _____

_____

Apprentice Permit #: _____

Apprenticeship Start Date _____

Directions for Supervisor / Professional Tattoo Artist:

- This form is to be completed while the apprentice demonstrates knowledge of each new task.
- These tasks are to be demonstrated while practicing as a tattoo artist.
- As each new task is mastered, the Supervisor / Professional Tattoo Artist should date, initial, and provide any comments for each subject on the task sheet.
- Upon completion of the apprenticeship program, a copy of this form and all documentation of experience, will be submitted to the BOH for review.
- Body Art Apprentice Time Sheet
    - A copy of the time card/sheet stating the date, time worked, training activity conducted, and total hours.
    - The time sheet must be signed, and dated by both the apprentice and initialed by the Supervisor / Professional Tattoo Artist named on the application.
    - Retain a copy for the BOH as evidence of experience.
- For each level of procedure the apprentice completes:
    - A description of the procedure
    - A picture of the body art
    - Number of hours it took to complete
        - ~~Recorded on the back of the customer consent form~~
        - Dated and signed by the Supervisor / Professional Tattoo Artist named on the application.
        - Retain a copy for the BOH as evidence of experience.

TASKS TO BE MASTERED BY THE APPRENTICE

Demonstrates Knowledge Of:

1. **Bloodborne Pathogen Standards**

   Supervisor Comments _____

   _____

   _____

   Date _____ Supervisor Initials _____

2. **Infection Control Standards of:**

   A. Workstation/premises

   Supervisor Comments _____

   _____

   _____

   Date _____ Supervisor Initials _____

   B. Instruments

   Supervisor Comments _____

   _____

   _____

   Date _____ Supervisor Initials _____

C. Machines

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

3. Infection Prevention Practices

A. Hand-Washing

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

B. Personal Protection Equipment

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

3. Asepsis

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

Tattoo Apprentice Task Sheet

4. **Proper Cleaning Techniques of:**

A. Instruments

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

B. Equipment

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

C. Environment

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

D. Workstation

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

5. **Proper Sterilization Technique:**

A. Pre-cleaning

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

B. Packaging/Loading

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

C. Storage of Instruments

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

6. **Proper Waste Disposal Of:**

A. Sharps

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

B. Contaminated

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

C. Regular

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

7. Can explain the content of Consent Forms and the complications that could result from tattoos

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

8. Can properly evaluate Health History Forms

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

9. Understands and **can explain proper aftercare instructions to a client**

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

10. Can explain proper steps to take in the event of an exposure incident

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

11. Can explain proper emergency procedure for:

A. Excessive Bleeding

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

B. Fainting

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

C. Exposure Incident

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

12. Proper Preparation of Workstation

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

13. Proper skin surface preparation

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

Skill Level Description and Apprentice Hours/Procedures Required

Tattoo Apprentice Task Sheet

75 Hours of Direct Observation

The apprentice should directly observe tattooing techniques of Professional Tattoo Practitioners. Attention should be paid to the clean-up and preparation procedures, sanitation and sterilization techniques, exposure control techniques practiced by the tattoo practitioner, hand-washing and glove use, machine maintenance, skin surface preparation and tattoo skills of the professional practitioner. Observation can only be done with the consent of the client.

Supervisor Comments _____

_____

_____

Date _____ Supervisor Initials _____

75 Hours of Workstation Clean-Up and Workstation Preparation

Some of these hours can be combined with the direct observation hours after the apprentice has learned workstation clean-up and preparation skills.

Supervisor Comments _____

_____

_____

_____

_____

Date _____ Supervisor Initials _____

Skill Level Description and Apprentice Hours/Procedures Required

Tattoo Apprentice Task Sheet

LEVEL 1

- **Minimum of 150 Procedures and 500 Hours of small, simple, single color pieces**

Supervisor Comments _____

_____

Date _____ Supervisor Initials _____

LEVEL 2

- **Minimum of 150 Procedures and 750 Hours of medium size (5"x5"), more complicated pieces of moderate difficulty.**

Supervisor Comments _____

_____

Date _____ Supervisor Initials _____

LEVEL 3

- **Minimum of 150 Procedures and 1000 Hours of larger more complicated pieces involving the blending of multiple colors, custom designs, cover-up work, and fineline tattooing.**

Supervisor Comments _____

_____

Date _____ Supervisor Initials _____

Some of the levels are allowed to overlap, but the apprentice should master a step prior to moving on to the next level. The apprentice is required to submit ten pieces from each level as evidence of experience.

I certify that the apprentice has completed the required number of hours and procedures, has displayed the techniques and knowledge of a professional tattoo artist, and has successfully completed the Apprenticeship Program as designed by the Arlington Public Health Department.

Supervisor Signature _____ Date _____

Apprentice Signature _____ Date _____

INK JAM
TATTOO STUDIO

12 PARK AVE, ARLINGTON MA ~ 781(316-2393) ~ WWW.INKJAMTATTOO.COM
CONSENT TO APPLICATION OF BODY ART PROCEDURE RELEASE AND WAIVER OF CLAIM
CONSENT TO TATTOO by an APPRENTICE

Please Initial Each Item:

___ I acknowledge that I have been given the full opportunity to ask any and all questions which I might have about obtaining of a tattoo from Ink Jam Tattoo Studio and that all of my questions have been answered to my full and total satisfaction.
___ I acknowledge that I have had a complete and satisfactory pre-procedural consultation prior to any body art procedure and health risks associated with it.
___ I acknowledge that I am not under the influence of drugs and alcohol.
___ I acknowledge that I have no history of hemophilia (bleeding) and/or I have consulted with the physician prior to receiving any tattoos.
___ I acknowledge that I have no history of skin disease, lesions, or sensitivities to soap or disinfectants.
___ I acknowledge that I have no history of allergies or adverse reactions to pigments, dyes, latex, or other sensitivities.
___ I acknowledge that I have no history of epilepsy, seizures, narcolepsy, or fainting.
___ I acknowledge that I am not using medications such as anticoagulants, which thin the blood or interfere with clotting.
___ I acknowledge that I am free of communicable diseases such a Hepatitis and/or HIV/AIDS.
___ I acknowledge that I am not pregnant.
___ I acknowledge that I have truthfully represented to Ink Jam Tattoo Studio that I am at least 18 years old.
___ I acknowledge receipt of written body art disclosures.
___ I acknowledge that infections and/or adverse reaction is possible, particularly in the event that I do not take proper care of my tattoo.
___ I acknowledge receipt of written instructions on the proper care of my tattoo and I acknowledge the necessity for following these instructions.
___ I acknowledge that variations in color and design may exist between my tattoo as selected by me and as ultimately applied to my body.
___ I acknowledge that a tattoo is a permanent change and that no representation has been made on the ability to later change or remove the tattoo.
___ I acknowledge that the obtaining of a body art procedure is my choice. I consent to the application of a tattoo.
___ **I acknowledge, and understand that an apprentice is tattooing me.**
___ I hereby give Ink Jam Tattoo Studio permission to publish any and all photos of my tattoo.
___ I hereby witness that all tattoo equipment (needles, tubes, inks, etc.) are new and sterile.
___ I hereby take responsibility for approving spelling of names and correctness of dates in my tattoo.

Name: _____

Address: _____

City/State/Zip: _____

Phone #: _____ **Email:** _____

Date of Birth: _____

Description of Body Art: _____

Body Part Where Tattoo is Located: _____

Artist Performing Tattoo: _____

Ink Jam Witness: _____ **Supervisor Initial:** _____

SIGNATURE: _____ **DATE:** _____

By signing this form, I agree to release and forever discharge and hold harmless Ink Jam Tattoo Studio and its owners, agents, independent contractors, employees, and apprentice from any and all claims, damages, or legal actions arising from or connected in any way with this body art procedure. I confirm that the above information was provided to me, that I do not have a condition, which will prevent me from receiving body art, that I consent to the body art procedure and am aware of the risks and that I was given a Disclosure Statement and an After Care Instruction sheet.

Level _____ **Date:** _____

Supervisor / Professional Tattoo Artist Comments:

_____

_____

_____

Photo of Tattoo:

Copy of License

Ink Jam Tattoo Studio
12 Park Avenue
Arlington, Ma. 02476
(781)-316-2393
www.inkjamtattoo.com

Body Art Disclosure Statements

This statement is to be given to all body art clients prior to performing any body art procedure.

TATTOO DISCLOSURE STATEMENT

As with any invasive procedure, tattooing may involve health risks. These risks may include to following:

- Pain, bleeding, swelling, infection, scarring of the area and nerve damage.
- Unsterile equipment and needles can spread infectious diseases. It is extremely important to be sure that all equipment is clean and sanitary before use.
- Tattoos and permanent makeup are not easily removed and in some cases may cause permanent discoloration; think carefully before getting a tattoo. There is also the possibility of an allergic reaction.
- The inks or dyes used for tattoos are color additives. Currently no color additives have been approved by the FDA for tattoos, including those used in permanent makeup.
- Blood donations cannot be made for one year after getting a tattoo or permanent makeup.

HEALTH HISTORY AND INFORMED CONSENT

The following conditions may increase health risks associated with receiving body art:

- Diabetes
- Hemophilia (bleeding)
- Skin diseases, lesions, or skin sensitivities to soaps, disinfectants, ect.
- History of allergies or adverse reactions to pigments, dyes, or other sensitivities.
- History of epilepsy, seizures, fainting, or narcolepsy.
- Use of medications such as anticoagulants (such as Coumadin and aspirin) which thin the blood and/or interfere with blood clotting.
- Hepatitis or HIV infection
- History of or suspicion of adverse reaction to latex or products containing latex.

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www.inkjamtattoo.com

TATTOO AFTERCARE INSTRUCTIONS

Treat your new tattoo as an open wound. Keep it clean. Do not touch healing tattoos without clean hands. Before cleaning the tattooed area, wash hands thoroughly with antibacterial soap and water.

Carefully remove the gauze bandage and tape. If the gauze sticks, use a tiny bit of warm water to remove. Do not rip off the bandage. As soon as you remove the dressing, wash your new tattoo thoroughly but gently with warm water and antibacterial soap. Do not pick or wipe off any scabs, whether the scab is dry or wet. The area will be tender, but it is important to remove any dried blood and fluids. This is one of the most important steps in the care of your tattoo. Do this daily to remove old ointment. When the tattoo has been thoroughly cleaned, gently pat it dry with a clean towel and allow it to air dry for at least 10 minutes.

After cleaning and allowing your tattoo to air dry for 10 minutes, massage a small amount of antibacterial ointment (such as Bacitracin, Neomycin-Polymyxin) into the tattoo. Gently rub the product in well, ensuring is has all been absorbed and creates a **very thin** covering which moisturizes the entire tattoo. Repeat cleansing and application of antibacterial ointment 2-4 times a day for 3 days. After 3 days, switch to unscented fragrance-free body moisturizer (such as Eucerin or Lubriderm.)

Avoid sunburn, salt or chlorinated pool water, hot tubs, saunas and steam baths while your tattoo is healing. Itching is expected. Do not scratch the tattoo.

The approximate average healing time for tattoos is 7-14 days. Human bodies are highly individual and healing times vary greatly. Your tattoo should not hurt much worse than a sunburn. If your tattoo causes more pain than a sunburn, please contact your tattooist and doctor immediately.

Follow these instructions carefully and you will have a crisp, bright tattoo for the rest of your life. Disregard them and it will not heal well and will not look as well as it should. If you are not sure about the way your tattoo is healing; then please give us a call or stop by and let us evaluate your tattoo's progress. Sometimes even a well cared for tattoo may need a small touch up. Touch ups may be needed for an area that did not heal well, or needs a little more color added. The tattoo will need at least 2 weeks to heal prior to any touch ups.

Your tattoo will be applied with sterile equipment, the procedure also with sterile equipment and non-toxic colors. We guarantee the workmanship. Healing and caring for your tattoo is YOUR responsibility.

CONSULT YOUR HEALTH CARE PROVIDER FOR:

(a) Unexpected redness, tenderness or swelling
(b) Rash
(c) Unexpected drainage
(d) Fever within the first 24-72 hours after procedure

Complaints may be filed with:
Arlington Board of Health
27 Maple Street
Arlington, Ma. 02476
(781)-316-3170

Massachusetts Department of Public Health:
(617)-983-6800

12. Application for Body Art Practitioner Permit

(A) No person shall practice body art or perform any body art procedure without first obtaining a practitioner permit from the Board. The Board shall set a reasonable fee for such permits.

(B) The annual fee for a body art practitioner permit shall be $200.

(C) A practitioner shall be a minimum of 18 years of age.

(D) A practitioner permit shall be valid from the date of issuance and shall expire no later than one year from the date of issuance unless revoked sooner by the Board.

(E) Application for a practitioner permit shall include:
(1) name;
(2) date of birth;
(3) residence address;
(4) mailing address;
(5) phone number;
(6) place(s) of employment as a practitioner; and
(7) training and/or experience as set out in (G) below.

(F) Each applicant for a body art practitioner permit shall appear at a regularly scheduled Board of Health meeting to present application.

(G) Practitioner Training and Experience

(1) In reviewing an application for a practitioner permit, the Board may consider experience, training and/or certification acquired in other states that regulate body art.

(2) Training for all practitioners shall be approved by the Board and, at a minimum, shall include the following:

(a) bloodborne pathogen training program (or equivalent) which includes infectious disease control; waste disposal; handwashing techniques; sterilization equipment operation and methods; and sanitization, disinfection and sterilization methods and techniques; and
(b) Current certification in First Aid and cardiopulmonary resuscitation (CPR).

Examples of courses approved by the Board include "Preventing Disease Transmission" (American Red Cross) and "Bloodborne Pathogen Training" (U.S. OSHA). Training/courses provided by professional body

art organizations or associations or by equipment manufacturers may also be submitted to the Board for approval.

(3) The applicant for a body piercing practitioner permit shall provide documentation, acceptable to the Board, that s/he completed a course on anatomy and physiology with a grade of C or better at a college accredited by the New England Association of Schools and Colleges, or comparable accrediting entity. This course must include instruction on the system of the integumentary system (skin).

(4) The applicant for a tattoo practitioner permit shall provide documentation, acceptable to the Board, that s/he completed a course on anatomy and physiology with a grade of C or better at a college accredited by the New England Association of Schools and Colleges, or comparable accrediting entity. This course must include instruction on the integumentary system (skin).

(2) The applicant for all practitioners shall submit evidence satisfactory to the Board of at least two years actual experience in the practice of performing body art activities of the kind for which the applicant seeks a body art practitioner permit to perform, whether such experience was obtained within or outside of the Commonwealth.

(H) A practitioner's permit shall be conditioned upon continued compliance with all applicable provisions of these rules and regulations.

4.03: continued

(3) No school shall permit a senior student to act as an instructor or to instruct a junior student.

(4) Students, upon graduation from school and pending examination, may work in licensed salons only after obtaining from the Board a temporary permit to do so.

(5) No students shall be permitted to enter a classroom unless their attire complies with the dress code established by the school.

4.04: Curriculum

(1) Hairdressing Program.

(a) Each school teaching hairdressing shall maintain a course of study of not less than 1,000 hours, extending over a period of not less than six months. No student shall be required to attend classes more than five days per week (Monday through Saturday).

(b) Every school shall maintain regular class hours with a daily schedule. Such schedule must be submitted to the Board for its approval.

(c) Every school shall maintain a course of practical training in:

Shampooing
Hairdressing
Marcel Waving (optional)
Finger Waving
Permanent Waving
Hair Coloring
Hair Cutting
Skin Care/Facial Grooming
Scalp Massage
Wig Instruction
Hair Straightening
Thermal Styling

(d) Every school shall furnish instruction in antisepsis, sterilization, sanitation, and the use of electrical apparatus and electricity as applicable to the practice of the various branches of cosmetology, and shall arrange courses devoted to each branch of cosmetology in accordance with the following outline of study and schedule of hours:

1. Outline of Study

Theory	Practical
Sanitation	Shampooing
Sterilization	Hairdressing
Hygiene	Marcel Waving (optional)
Bones	Finger Waving
Muscles	Permanent Waving
Nerves	Wig Instruction
Vascular System	Hair Straightening
Circulation	Hair Coloring (dyeing, tints rinses, bleaching pack, reconditioning)
Skin	
Nails	Hair Cutting
Electricity	Manicuring
Shop Management	Skin Care/Facial Grooming
Personal Hygiene	Scalp Massage

10. Issuance and holding of a Tobacco and Nicotine Delivery Product Sales Permit shall be conditioned on an applicant's on-going compliance with current Massachusetts Department of Revenue requirements and policies including, but not limited to, minimum retail prices of tobacco products.

11. A Tobacco and Nicotine Delivery Product Sales Permit will not be renewed if the permit holder has failed to pay all fines issued and the time period to appeal the fines has expired and/or has not satisfied any outstanding permit suspensions.

12. Mandatory Retailer Training: As part of the Tobacco and Nicotine Delivery Product Sales Permit renewal process, permit holders are required to send at least one (1) employee who works on the premises to a tobacco retailer training conducted by the Arlington Board of Health once per year. The Arlington Board of Health will schedule the trainings and notify permit holders of the date (s). Failure of the establishment to send a retailer may result in suspension or revocation of a permit to sell tobacco and nicotine delivery products in the Town of Arlington.

13. Maximum Number of Tobacco and Nicotine Delivery Product Sales Permits: The maximum number of permits allowed shall be nineteen (19), reduced by the number of permits not renewed pursuant to Section E (14). New applicants for permits who are applying at a time when the total number of outstanding permits meets or exceeds the maximum number of permits allowed will be placed on a waiting list and will be eligible to apply for a permit on a "first-come, first-serve" basis as permits are either not renewed or returned to the Arlington Board of Health.

14. Expiration of Waiting List: Any applicant that is currently on the waiting list as of January 1, 2018 may apply for a permit if and when an existing permit is either not renewed or returned to the Arlington Board of Health. However, this opportunity will expire on January 1, 2020, at which point the Arlington Board of Health will no longer maintain a waiting list. In addition, as of January 1, 2018, the Arlington Board of Health will no longer add applicants to the existing waiting list.

15. Any permit holder who has failed to renew an existing permit within 30 days of expiration will be treated as a first-time permit applicant.

16. A purchaser of a business that holds a current Tobacco and Nicotine Delivery Product Sales Permit at the time of the sale of said business may apply, within sixty (60) days of such sale, for the permit held by the Seller if the Buyer intends to sell tobacco products and/or nicotine delivery products. An owner of a business that holds a current Tobacco and Nicotine Delivery Product Sales Permit that intends to change the physical location of the business in Arlington must notify the Board of Health in writing thirty (30) days before such change of location occurs. The permit will be reissued reflecting the continuation of said business at the new address. Any permit holder who has failed to notify the Board of Health in writing thirty (30) days before changing the physical location of the business will be treated as a first-time applicant.

Town of Arlington
Department of Health and Human Services
Office of the Board of Health
27 Maple Street
Arlington, MA 02476

Tel: (781) 316-3170
Fax: (781) 316-3175

MEMO

To: Board of Health
From: Natasha Waden, Public Health Director
Date: April 5, 2018
RE: Rock Removal Regulations

As a result of ongoing complaints precipitated by construction projects over the last few years, Town Officials have worked with residents and developers over the last year to address some of these concerns. Despite their efforts, which have led to changes and amendments to town bylaws, residents are still concerned about the generation of dust and noise levels at construction sites. As a result, Town Manager Adam Chapedline has requested that the Board of Health considers developing Rock Removal Regulations. These regulations would require developers to obtain a permit from the Health Department and comply with conditions related to noise and dust generation at the construction site. At our next meeting we can discuss how to proceed on this matter.

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MEMO

To: Board of Health Members

From: Kylee Sullivan, Health Compliance Officer

Date: April 5, 2018

RE: Draft Dumpster Regulations

Enclosed please find an updated draft for Arlington's *Wastehauler and Dumpster Regulations and for the Removal and Transportation of Solid Waste or Recyclables*. By researching the permitting of dumpsters and wastehaulers in surrounding municipalities such as Belmont, Lexington, Medford, Cambridge, and Somerville, these updates contain current best practices enforced by our neighboring communities. Included in these regulations are safeguards to prevent dumpsters from being accessible food sources for rodents and other wildlife. This is especially important due to the drastic increase in rodent activity observed across Town over the past few years. These regulations also include information provided in model regulations for municipalities to comply with the *Massachusetts State Waste Ban: 310 CMR 19.017*. DPW Recycling Coordinator, Charlotte Milan, has been involved in the drafting of these regulations and continues to be a helpful resource. Routine dumpster inspections during 2017 found that the majority of dumpsters in Town are poorly maintained and create public health nuisances through pest infestations and noxious odors. Amending the current dumpster and wastehauler regulations will reduce such nuisances that pose a public health risk to our community. Please also find the Town's current *Dumpster Regulations and for the Removal and Transportation of Garbage, Rubbish, Offal, or Other Offensive Substances* included for your reference.

Town of Arlington
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Wastehauler and Dumpster Regulations and for the Removal and Transportation of Solid Waste or Recyclables

Section 1: Statement of Purpose

Whereas the Arlington Board of Health has seen an 80% increase in rodent complaints throughout the Town since 2015;

Whereas there are 197 Food Establishments permitted in Town during 2018;

Whereas in 2014, 258.5 million tons of Municipal Solid Waste (MSW) was generated nationally[1];

Whereas in 2014, 14.9% of America's MSW was food waste[2];

Whereas on average in 2013 each American produced 4.4 pounds of waste per day[3];

Whereas Massachusetts Waste Ban regulations, as specified in 310 CMR 19.017, are in place to reduce adverse environmental impacts that may result from the human-generated solid waste;

Now, therefore it is the intention of the Arlington Board of Health to regulate dumpsters and wastehaulers that transport solid waste or recyclables to ensure that they are in compliance with the Massachusetts Waste Ban regulations and uniformly comply with permit requirements established by the Town of Arlington.

Section 2: Scope of Authority

This regulation is promulgated pursuant to the authority granted to the Arlington Board of Health by Massachusetts General Laws, Chapter 111, Section 31 that "Boards of Health may make reasonable health regulations".

Section 3: Applicability

These regulations shall apply to all commercial and residential dumpsters within the Town of Arlington, Massachusetts. Temporary dumpsters utilized in conjunction with building permits issued by

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[1] United States Environmental Protection Agency, (EPA) (2016), *Advancing Sustainable Materials Management: 2014 Tables and Figures*. Retrieved from: https://www.epa.gov/sites/production/files/2016-11/documents/2014_smm_tablesfigures_508.pdf

[2] United States Environmental Protection Agency, (EPA) (2016*), Advancing Sustainable Materials Management: 2014 Tables and Figures*. Retrieved from: https://www.epa.gov/sites/production/files/2016-11/documents/2014_smm_tablesfigures_508.pdf

[3] United States Environmental Protection Agency, (EPA) (2016), *Municipal Solid Waste*. Retrieved from: https://archive.epa.gov/epawaste/nonhaz/municipal/web/html/

Inspectional Services shall not fall under the jurisdiction of these regulations. All dumpsters utilized by a permitted food establishment in the Town of Arlington shall comply with both the regulations outlined herein and all applicable requirements as outlined by the current Food and Drug Administration (FDA) Food Code edition enforced in the Town of Arlington.

Section 4: Definitions

Board: The Board of Health or its agent or designee.

Composting: A process of accelerated biodegradation and stabilization of organic material under controlled conditions yielding a product which can be safely used, as those terms are or may be defined by *310 CMR 19.00: Solid Waste Management.*

Dumpster: Any container (other than a conventional trash can with lid) used for the outside storage of solid waste, recyclables, garbage, rubbish, organic matter, or refuse of any sort. This definition excludes temporary construction dumpsters permitted by Inspectional Services.

Garbage: The animal, vegetable or other organic waste resulting from the handling, preparing, cooking, consumption or cultivation of food, and containers and cans which have contained food unless such containers have been cleaned and prepared for recycling.

Owner: Any person, including a lessee or mortgagee in possession, who alone or severally with others, has lawful title to or lawful possession, care or control of any property on which a dumpster is located or proposed to be located. Owner also includes any authorized agent of such person.

Private Wastehauler: Any person, who, for compensation, supplies, maintains or services one or more dumpsters, or removes, transports or disposes of the contents thereof who is not apart of the Town's wastehauler contract.

Recycleables: A material that is banned from disposal in the Commonwealth of Massachusetts pursuant to *310 CMR 19.017: Waste Bans*. Mixed paper, cardboard, glass, metal, plastic containers are priority materials of this regulation.

Rubbish: Combustible and noncombustible waste materials, except garbage, and includes but is not limited to such material as paper, rags, cartons, boxes, wood, excelsior, rubber, leather, tree branches, yard trimmings, grass clippings, tin cans, metals, mineral matter, glass, crockery, dust, and the residue from the burning of wood, coal, coke and other combustible materials.

Solid Waste: Useless, unwanted or discarded non-recyclable solid or liquid wastes, excluding items restricted from disposal in Massachusetts, as defined by Table *310 CMR 19.017 (3)* of the Massachusetts Solid Waste regulations (*310 CMR 19.017).*

Waste Ban Materials: All materials designated as banned from disposal in the Commonweath of Massachusetts pursuant to *310 CMR 19.017*: *Waste Bans*, including: asphalt pavement, brick and concrete, cathode ray tubes, clean gypsum wallboard, ferrous and non-ferrous metals, glass and metal containers, lead acid batteries, leaves and yard waste, recyclable paper, cardboard and paperboard, single resin narrow-neckwed plastics, treated and untreated wood and wood waste (banned from landfills only), white goods (large appliances), and whole tires (banned from landfills only).

Wastehauler: Any person, who, for compensation, supplies, maintains or services one or more dumpsters, or removes, transports or disposes of the contents thereof in accordance with the Town's wastehauler contract.

Section 5: Dumpster Permit Application

5.1 No dumpster shall be used or kept in the Town of Arlington after January, 2019 unless an application is submitted to the Board of Health and a permit is issued by the Board allowing the use of such dumpster. All permits shall expire at the end of the calendar year in which they are issued, and may be renewed annually with the application provided by the Board. There shall be a fee of $100.00 payable for said permit.

Section 6: Wastehauler Permit Application

6.1 No contractor, firm, or person shall supply a dumpster service in the Town of Arlington for the purpose of storage, removal, or transporting of solid waste or recyclables without first obtaining a wastehauler permit from the Board. All permits shall expire at the end of the calendar year in which they are issued, but may be renewed annually with the application provided by the Board. There shall be a fee of $11 0.00 payable for said permit.

Section 7: Dumpster Regulations

7.1 Each dumpster must be located at a distance from the lot line spo as to not interfere with the safety, convenience, or health of abutters or residents. Dumpster location must be approved by the Board.

7.2 Each dumpster must be situated so as not to obstruct the view of flowing traffic.

7.3 When deemed necessary by the Board, it may be required that a dumpster site be enclosed or screened by the property owner or authorized agent.

7.4 Each dumpster must be of sufficient size and capacity to eliminate overflowing, and the property owner or authorized agent of the premises utilizing the service must take appropriate action immediately to empty contents when full.

7.5 All dumpsters must have a tight-fitting lid or cover, which shall be kept closed at all times except when being filled, cleaned or emptied. Each dumpster shall be constructed in such a way as to

be leak-proof. If drain plugs are provided, they must be tight-fitting so as to prevent the leakage of liquid. All dumpsters must be maintained in good condition, without defect, as to prevent pest activity.

7.6 Any dumpster used for the disposal of liquids or organic matter shall be emptied as necessary to prevent insect or pest attraction.

7.7 The Board may order dumpster capacity size changes and/or additional pickups if in their opinion they find it necessary.

Section 8: Dumpster Permittee Responsibilities

8.1 The owner or agent of the dumpster shall have his/her business name and telephone number conspicuously displayed on the dumpster.

8.2 It shall be the responsibility of the owner or agent whose property is being serviced to maintain the dumpster area free of odors, scattered debris, overflowing debris, and all other nuisances. It shall also be the responsibility of the property owner or agent being serviced to maintain the dumpster area free from any condition that may be considered an attraction for rodents or other pests.

8.3 Dumpsters must be maintained in good condition. Rust holes, uncovered drain caps, and other physical evidence of neglect that allows rodents and other animals access to the dumpster contents are not permitted. Owners who have a history of poor maintenance shall be required to work with their contractor and swap out the dumpster for one that meets these regulations.

8.4 Dumpsters must be placed on pavement or concrete, not soil. The location must be approved by the Arlington Board of Health.

8.5 Food service establishments must also comply with *105 CMR 590.000*, the State Sanitary Code.

Section 9: Wastehauler Permittee Responsibilities

9.1 The dumpster wastehauler shall have the dumpster deodorized, washed or sanitized as directed by order of the Board as necessary to preclude pest attraction and activity.

9.2 The dumpster wastehauler shall have his/her business name and telephone number conspicuously displayed on the dumpster.

9.3 All permitted wastehaulers must be in compliance with applicable federal, state, and local laws. Each wastehauler vehicle must meet all Department of Transportation safety requirements at all times.

9.4 All materials must be securely contained in the vehicle. Littering or leaking shall be considered a violation of this regulation.

Section 10: Madatory Recycling

10.1 This regulation is intended to support and align with the Townof Arlington's Mandatory Recycling Bylaw as outlined in Massachusetts Waste Ban regulations *310 CMR 19.017*. All recycling must be in compliance with the requirements outlined in the Town's contracted wastehauler services.

Section 11: Violations; Enforcement

11.1 These regulations apply to all dumpsters and wastehaulers in the Town of Arlington whether for residential, commercial, or industrial use.

11.2 The Board is authorized to inspect a permitted dumpster or a permitted wastehauler's truck and load at any time. The Board also has the right to require weight slips or confirmation of disposal of solid waste or recyclables.

11.3 Wastehauler permits may be suspended or revoked by the Board for failure of the wastehauler to comply with the requirements of these regulations.

11.4 The Board may attach any conditions to the dumpster service permit that it deems would serve the interest of the safety, health, welfare, or quality of life of the citizens of the Town of Arlington.

11.5 The Board may, by written decision, vary the application of any provision of these regulations with respect to any particular case, when the enforcement thereof would do manifest injustice; provided that any such decision of the Board shall not conflict with the express purpose of these regulations. Any variance shall, while it is in effect, be available to the public during normal business hours in the Health Department Office.

11.6 Any person who violates the terms of these regulations shall be subject to a fine of $50.00 for the first offense and $100 for each subsequent offense under the non-criminal disposition authorized by M.G.L. Chapter 40 Section 21D and Town bylaw Title VIII, Article 3 Section 7. Each day shall constitute a separate offense.

11.7 If any provision of these regulations is declared invalid or unenforceable by any court of competent jurisdiction, the other provisions of the regulations shall not be affected thereby, but shall continue in full force and effect.

11. Effective Date

This regulation shall take effect on April 11, 2018.

1. _____ Marie Walsh-Condon, MD

2. _____ Kenneth Kohlberg, JD, MPH

3. _____ Kevin Fallon, DVM

Town of Arlington
Department of Health and Human Services
Office of the Board of Health
27 Maple Street
Arlington, MA 02476

Tel: (781) 316-3170
Fax: (781) 316-3175

The Board of Health, Town of Arlington, Massachusetts in accordance with, and under the authority granted by Sections 31A and 31B of Chapter 111 of the General Laws of the Commonwealth of Massachusetts hereby adopted the following rules and regulations at a meeting of the Board held on March 19, 1985.

Effective Date: These regulations shall take effect on July 1, 1985. Revised December 9, 1998.

Dumpster Regulations and for the Removal and Transportation of Garbage, Rubbish, Offal, or Other Offensive Substances

1. Definitions:

   Board: The Board of Health or its agent or designee.

   Dumpster: Any container (other than a conventional trash can with lid) used for the outside storage of garbage, rubbish, or refuse of any sort.

2. Each dumpster must be located at a distance from the lot line so as not to interfere with the safety, convenience, or health of abutters or residents. Dumpster location must be approved by the Board.

3. When deemed necessary by the Board, it may be required that a dumpster site be enclosed or screened by the property owner or authorized agent.

4. All dumpsters must have lids that remain closed at all times when not in use.

5. Each dumpster must be of sufficient size and capacity to eliminate overflowing, and the property owner or authorized agent of the premises utilizing the service must take appropriate action immediately to empty contents when full.

6. Each dumpster must be situated so as not to obstruct the view of flowing traffic.

7. It shall be the responsibility of the owner or agent whose property is being serviced to maintain the dumpster area free of odors, scattered debris, overflowing, and all other nuisances.

8. No contractor, firm, or person shall supply a dumpster service in the Town of Arlington for the purpose of storage, removal, or transporting of garbage, rubbish, offal, or other offensive substances without first obtaining a dumpster service permit from the Board. All permits shall expire at the end of the calendar year in which they are issued, but may be renewed annually on application as herein provided. There shall be a fee of $100.00 payable for said permit.

9. The contractor shall have his/her name and business telephone number conspicuously displayed on the dumpster.

10. The emptying of the dumpster contents on residential property by the contractor shall not commence before 7:00 a.m. and not continue after 10:00 p.m. The Board may modify these hours in a more restrictive fashion, if in its reasonable judgment it is convinced that the public health, safety, or welfare would be better served. The Board shall be guided in this regard by the location, nearness to residential property, frequency of emptying, resulting noise an other factors which it considers appropriate.

11. The dumpster contractor shall have the dumpster deodorized when emptied or if necessary, washed or sanitized as directed by order of the Board.

12. These regulations apply to all dumpsters in the Town of Arlington whether for residential, commercial, or industrial use.

13. Dumpster service permits may be suspended or revoked by the Board for failure of the dumpster contractor to comply with the requirements of these regulations.

14. The Board may attach any conditions to the dumpster service permit that it deems would serve the interest of the safety, health, welfare, or quality of life of the citizens of the Town of Arlington.

15. The Board may, by written decision, vary the application of any provision of these regulations with respect to any particular case, when the enforcement thereof would do manifest injustice; provided that any such decision of the Board shall not conflict with the express purpose of these regulations. Any variance shall, while it is in effect, be available to the public during normal business hours in the Health Department office.

16. Any person who violates the terms of these regulations shall be subject to a fine of $50.00 for the first offense and $100 for each subsequent offense under the non-criminal disposition authorized by M.G.L. Chapter 40 Section 21D and Town By-law Title VIII, Article 3 Section 7. Each day shall constitute a separate offense.

Arlington Board of Health

Michael Fitzpatrick, DMD, Chair
Gregory Leonardos
Marie Walsh Condon, MD

Town of Arlington
Department of Health and Human Services
Office of the Board of Health
27 Maple Street
Arlington, MA 02476

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MEMO

To: Board of Health
From: Natasha Waden, Public Health Director
Date: April 5, 2018
RE: Adult Use Marijuana Regulations

As you may be aware, the Cannabis Control Commission promulgated regulations in March for Adult Use of Marijuana. As such, our Office has begun receiving inquiries from parties interested in opening a Marijuana establishment in Town. Although the Town currently has a moratorium in place for the operation of recreational marijuana establishments, this tentatively expires on June 30th, 2018. As a result, the Board must consider whether or not to pursue regulations for Adult Use Marijuana Establishments. The Mass Association of Health Boards (MAHP) has put together the attached regulation *(Regulation To Ensure The Sanitary and Safe Operation Of Marijuana Establishments and The Sale of Marijuana)*. In speaking with the Belmont Health Director, I was informed that they passed a similar regulation last month. It is also my understanding that other Boards of Health in surrounding communities may be considering their adoption.